EXHIBITS 15-44 TO THE DECLARATION OF JEFFREY B. COOPERSMITH IN SUPPORT OF DEFENDANT RAMESH BALWANI'S OMNIBUS MOTIONS IN LIMINE

EXHIBIT 15

Theranos CBC with Differential Assay Validation

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Theranos RBC Count Assay

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1. Overview

The clinical value of red blood cell (RBC; erythrocyte) counts has been demonstrated as a fundamental diagnostic and monitoring tool for a broad spectrum of pathologies in numerous studies. In the clinical laboratory, manual counts using hemocytometer and a light microscope have been largely replaced by automated flow based devices that use impedance or optical methods for cell detection (Greer, 2008). Many of these devices use isovolumetric sphering of cells to ensure that impedance or optical scatter can be accurately translated to cell volume or related properties (Kim, 1983). In general, automated hematology analyzers have been shown to be quite accurate, precise and robust for normal samples. However, spuriously high and low counts are often observed in a number of clinical situations. For example, use of purely physical property thresholds such as size (from impedance) or light scatter (from optical measurement) leads to leukocytes (WBCs) being counted as RBCs in samples with elevated WBC count (Zandecki M, 2007). Similarly, confusion between giant platelets and RBCs and small RBCs (microcytes) and platelets can lead to spuriously high and low RBC counts respectively (ICSH, 1982). Consequently, the reliability of current automated hematology analyzers for pathological samples in a clinical setting is less than desired.

The Theranos RBC assay has been designed to address many of the issues mentioned above. Fundamentally, a specific surface marker CD235a (glycophorin A) was selected based on numerous reports in literature for positive identification of RBCs (Blanchard, 1982) (Mohandas, 1992). Further, a zwitterionic surfactant based buffer was developed to allow isovolumetric sphering of erythrocytes and accurate volumetric measurement.

In this document, a flow cytometry based counting assay is validated against Abbott Cell-Dyn Ruby, an automated hematology analyzer.

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2. Principle

In this assay, red blood cells (RBCs, erythrocytes) are identified by fluorescently conjugated antibodies that recognize the antigen CD235a (also called glycophorin A). CD235a is abundantly expressed on the surface of RBCs ($5 - 9 \times 10^5$ copies per cell) and anti-CD235a antibodies have been extensively used for selective labeling of RBCs in a variety of applications (Mohandas, 1992). International Council for Standardization in Haematology (ICSH) reference method for platelet counts also recommends the use of CD235a for identification of RBCs (2001).

The unique biconcave shape of RBCs creates challenges for measuring RBC light scatter. Kim and Ornstein pioneered the use of low concentration buffered isotonic surfactant solution for isovolumetric sphering of RBCs. The surfactant molecules are believed to insert in the cell membrane and cause the bending modulus of the membrane to drastically decrease leading to sphering of the cell with membrane present in microfolds on the cell membrane. This approach has been extensively used by many manufacturers of hematology analyzers. In this assay RBCs are isovolumetrically sphered by incubation with a zwitterionic detergent (N-Dodecyl-N,N-dimethyl-3-ammonio-1-propanesulfonate, or DDAPS) and then fixed with a cross-linking fixative such as glutaraldehyde or formaldehyde.

To determine the number of RBCs per unit volume of whole blood, a known number of polystyrene microbeads are added to the sample to be used as a counting standard.

Thus, in this assay, whole blood is added to a solution containing fluorescently conjugated anti-CD235a antibodies and polystyrene microbeads, incubated to allow the antibodies to bind to the cells, then isovolumetrically sphered, fixed, and analyzed on a flow cytometer (BD Biosciences LSRFortessa, BD Biosciences Accuri, or Millipore Guava). The fluorescence intensity and light scatter information is captured in data files generated by the flow cytometer. This data is analyzed in multiple dimensions to allow for unambiguous gating of the RBC events and the bead events (See Figure below).

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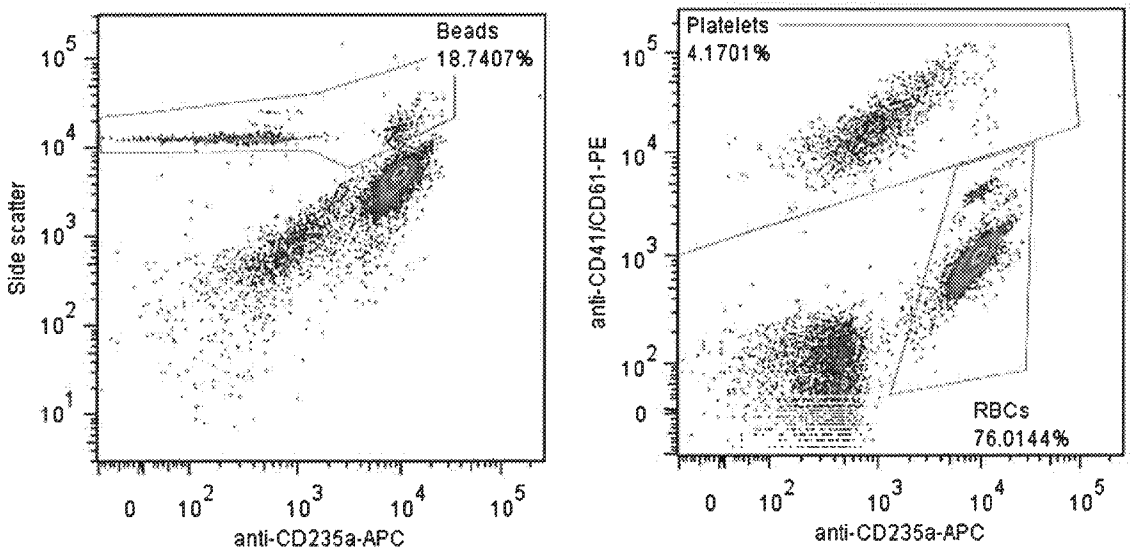

The format of the assay is in a multiwell microtiter plate so that sample preparation can be carried out on 24 or more samples at a time. The RBC count is calculated by determining the number of CD235a-positive events and the number of microbeads, and using the following formula to calculate the RBC concentration present in the whole blood that was tested.

$$RBC\ count\ (cells/L) = \left(\frac{CD235a\ positive\ events}{bead\ events}\right)(number\ of\ beads\ in\ reagent)$$

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3. Method Characterization

a. Precision:

CLSI standard EP05-A2 defines precision as the closeness of agreement between independent test/measurement results obtained under stipulated conditions. The term stipulated conditions encompasses a wide variety of contexts encountered in the process of clinical analysis. For the purpose of this validation study, precision was measured and characterized in the following contexts:

- within plate (or run) precision
- across plate (or run) precision
- within day precision
- between day precision

The main objective behind characterization of precision under the above conditions is to demonstrate that this method is robust to the different sources of variation inherent in the analytical method.

1. Within plate (or run) precision: Sixteen replicates of the same sample were analyzed on an assay plate. The coefficient of variation across these replicates characterizes the within run precision for this method.

RBC	*plate 1*	*plate 2*	*plate 3*
Mean of 16 replicates ($x10^{12}$ cells/L)	5.11	5.13	5.11
CV (%)	2	2.6	2.2
Acceptable CV (%)	< 3.5	< 3.5	< 3.5
Pass/Fail	Pass	Pass	Pass

2. Across plate (or run) precision: The foregoing data also allows us to characterize the across run precision, as the three plates had the same sample across them. Across all 16 x 3 = 48 replicates of this sample, the coefficient of variation was 2.26%. Further, in a separate study, three separate samples were analyzed in replicates of ≥ 31 each to establish the standard deviation of the measurement. The results from this study are included in the table below.

Date	*Donor*	*Replicates*	*Recovery*	*CV*	*Acceptable CV*	*Pass/Fail*
20130814	307	48	100.0	2.3	< 3.5	Pass
20130820	244	32	99.8	2.6	< 3.5	Pass
20130823	283	31	101.0	2.6	< 3.5	Pass

3. Within day precision and between day precision: For enumeration assays such as this RBC assay, the dependence of imprecision on analyte concentration is determined by the number of particles enumerated in a fixed dilution and counting scheme. At lower concentrations, fewer particles are enumerated and the imprecision in the point

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estimate of particle concentration increases (governed by Poisson distribution). However, for RBC the normal range is very narrow and consequently for all samples that fall in the normal range a significant number of particles is enumerated. Hence the concentration dependence of impression can be ignored. This argument is presented here to lay the basis for using sample recovery across different donors and different days as a way to characterize within and between day precision. In the table below, several plates run over several days have been combined and compared based on recovery. The variation in within-day precision can be clearly seen. The last column shows coefficient of variation calculated by aggregating all data points over different days.

Date	*Mean recovery (%)*	*CV (%)*	*Number of data points*
2013-08-20	98.3	2.6	32
2013-08-21	99.4	1.7	15
2013-08-22	100.2	3.0	62
2013-08-23	101.2	2.7	44
2013-08-25	99.8	2.5	8
2013-08-26	100.9	3.0	22
2013-08-27	101.1	2.9	32
2013-08-29	100.4	4.0	7
2013-08-30	99.2	2.8	31
2013-09-01	100.9	3.4	17
2013-09-02	99.9	3.1	19
2013-09-03	101.3	3.3	41
2013-09-05	102.9	3.1	32
Across all days	**100.5**	**3.2**	**362**
Acceptable CV (%)		**< 3.5**	
Pass/Fail		**Pass**	

b. Establishing the Analytical Measurement Interval or Linearity

CLSI guidance document H26AE defines the analytical measurement interval or analytical measurement range as the range of analytical values that a method can directly measure on the specimen without any dilution, concentration, or other pretreatment not part of the usual assay process. The aim of this part of the validation program was to establish an analytical measurement range significantly wider than the typical clinically reportable interval. In effect, this implies that the said method will provide sensible results, without dilution, concentration or other pretreatment for any sample which the laboratory wishes to analyze. To this end, fresh whole blood samples were manipulated to yield a range of RBC concentrations from 0.026 to 8.26 x 10^{12} cells/L. This

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range is significantly wider than any expected physiological range. These samples were processed in the usual way and analyzed for RBC concentration. Graphical representation and regression statistics for this dataset are shown in Figure 1. The goodness of fit establishes the "linearity" or the analytical measurement interval for this assay over 0.026 to 8.26 x 10^{12} cells/L.

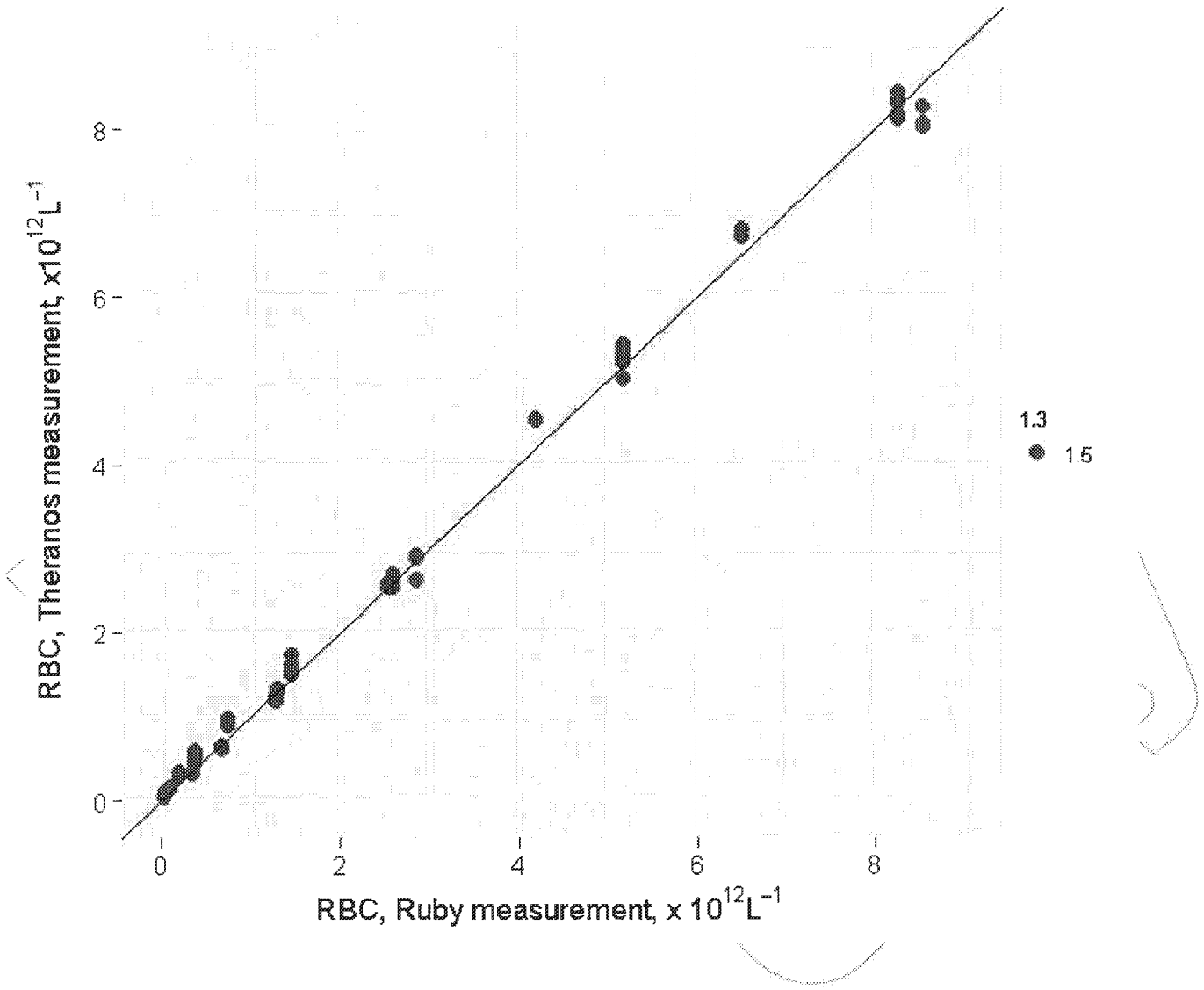

Figure 1 Concordance between Theranos and Ruby measurements showing linearity over the analytical range

Parameter	*Value*
Slope , [95% C.I.]	0.988, [0.975, 1.000]
Intercept , [95% C.I.]	0.077, [0.028, 0.128]
R^2	0.997

c. Limit of blank (LoB) and carryover

Since the Theranos assay system uses a flow cytometer as the analytical device for enumeration of red blood cells, carryover from one sample to the next is a distinct possibility. In spite of including a wash step between two consecutive samples, a small finite amount of carryover is unavoidable. The impact of carryover is characterized as the change in the measured value of a 'low' sample when it is run subsequent to a 'high' sample. This study was performed together with characterization of the limit of blank because the effective limit of blank strongly depends upon carryover. For these studies, 8 blank samples were run consecutively and analyzed to get the limit of blank with no carryover considerations. Next, alternate high (RBC ~ 4-5 x 10^{12}/L) and blank samples were run to quantify the limit of blank with carryover.

Parameter	*Value*	*Unit*
Limit of blank, no carryover	0.0003 ± 0.00013	x 10^{12}/L
Limit of blank, with carryover	0.022 ± 0.0055	x 10^{12}/L
Limit of blank, with carryover as percent of concentration of prior sample	0.45 ± 0.011	%

It is worth noting here that one of the reasons the limit of blank and carryover are significantly lower in the Theranos assay system as compared to predicate devices (where the norm is >1%, typically 1.5%) because of the specific epitope-based cell identification method used here. Due to epitope based identification, for a particle to be classified as a red cell, it must stain positive for CD235-APC and have side scatter in the correct range. Spurious events that satisfy these conditions are much fewer—hence the negligible limit of blank. Carryover is low due to extensive washes run after each sample run.

d. Limit of detection (LoD)

CLSI guidance document EP17-A2 defines the limit of detection (LoD) as the measurand quantity value, obtained by a given measurement procedure, for which the probability of falsely claiming the absence of a measurand in a material is β, given a probability α of falsely claiming its presence. For the purpose of this validation program, α and β were selected to be 0.05. Guidelines from

section 5.3.3 were used for designing the experiments and analyzing data. Briefly, three low level samples were contrived from fresh whole blood at concentrations ranging from 0.026 to 0.225 $x10^{12}$ /L. These samples were analyzed in quadruplicate along with blanks. From these data:
LoB = 0.0003 ($x10^{12}$ /L)
J = number of low level samples run = 3 (consider only the lowest here)
L = number of results from these J samples = 12 (quadruplicate)
SD_L = standard deviation of all the L low level samples

$$LoD = LoB + SD_L\left(\frac{1.645}{1-\frac{1}{4(L-J)}}\right) = 0.0038\ x\ 10^{12}\ cells/L$$

The limit of detection therefore is significantly lower than expected value for any physiological sample.

e. Limit of Quantification (LoQ)

CLSI guidance document EP17A2E defines the limit of quantification (LoQ) as the lowest amount of measurand in a material that can be quantitatively determined with stated accuracy under stated experimental conditions. Accuracy goals therefore need to be stated *a priori*. Then trial value of LoQ is picked based on the desired value the laboratory wants to claim. Based on the analytical measuring interval, a value of 0.125 x 10^{12}/L was selected as the target LoQ.

Accuracy goal was stated using the Westgard model:

$$TE = |bias| + 2\ SD$$

where, TE = the total error, bias is calculated as difference of measured value from the reference value of the sample at LoQ and SD is the standard deviation of measured values. The total error goal for this assay was defined to be 15% of the reference value of the LoQ sample.

The data and calculations tabulated below show that a sample at 0.121 x 10^{12} /L can be measured with a total error of less than 15%.

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RBC, measured ($x10^{12}$/L)	*Reference value ($x10^{12}$/L)*	*Absolute bias ($x10^{12}$/L)*
0.122	0.121	0.001
0.126	0.121	0.005
0.119	0.121	0.002
0.118	0.121	0.003
0.132	0.121	0.011
0.125	0.121	0.004
0.112	0.121	0.009
0.116	0.121	0.005
0.123	0.121	0.002
0.123	0.121	0.012
0.112	0.121	0.009
0.116	0.121	0.005
SD = 0.006		Mean = 0.0048
TE = 0.0048 + 2 x 0.006 = 0.0173 = 14.3% of Ref value		

f. Interference (pathological samples)

CLSI guidance document H26A2E defines interference as an artifactual increase or decrease in apparent concentration or intensity of a measurand due to the presence of a substance that reacts nonspecifically with either the detecting reagent or the signal itself. In traditional hematology analyzers where RBCs are detected based on their size or light-scattering properties, presence of similar sized particles is the primary reason for interference. In the Theranos assay, red cells are detected based on their light scattering properties but identified as red cells based on their positive staining with CD235a. Consequently, interferants such as giant platelets or small leukocytes, microcytes, etc. are not expected to have an impact on the assay. One major source of interference is the possibility that the antibody used for detecting RBCs in this assay does not recognize the glycophorin a on a certain sample. In more than 1000 samples that have been analyzed by our laboratory over the last 2 years during which this assay was under development, not a single instance of absence of CD235a staining has been observed.

Pathological samples collected in the morning were sourced from UCSF laboratories and analyzed on the same day. The following conditions were reported in the UCSF laboratory reports.

Condition	*Number of samples*

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Anemia (RBC < 3.9 x 10^{12}/L)	90
Macrocytosis (MCV > 100 fL)	11
Microcytosis (MCV < 80 fL)	9
Anisocytosis (RDW > 14.6%)	52

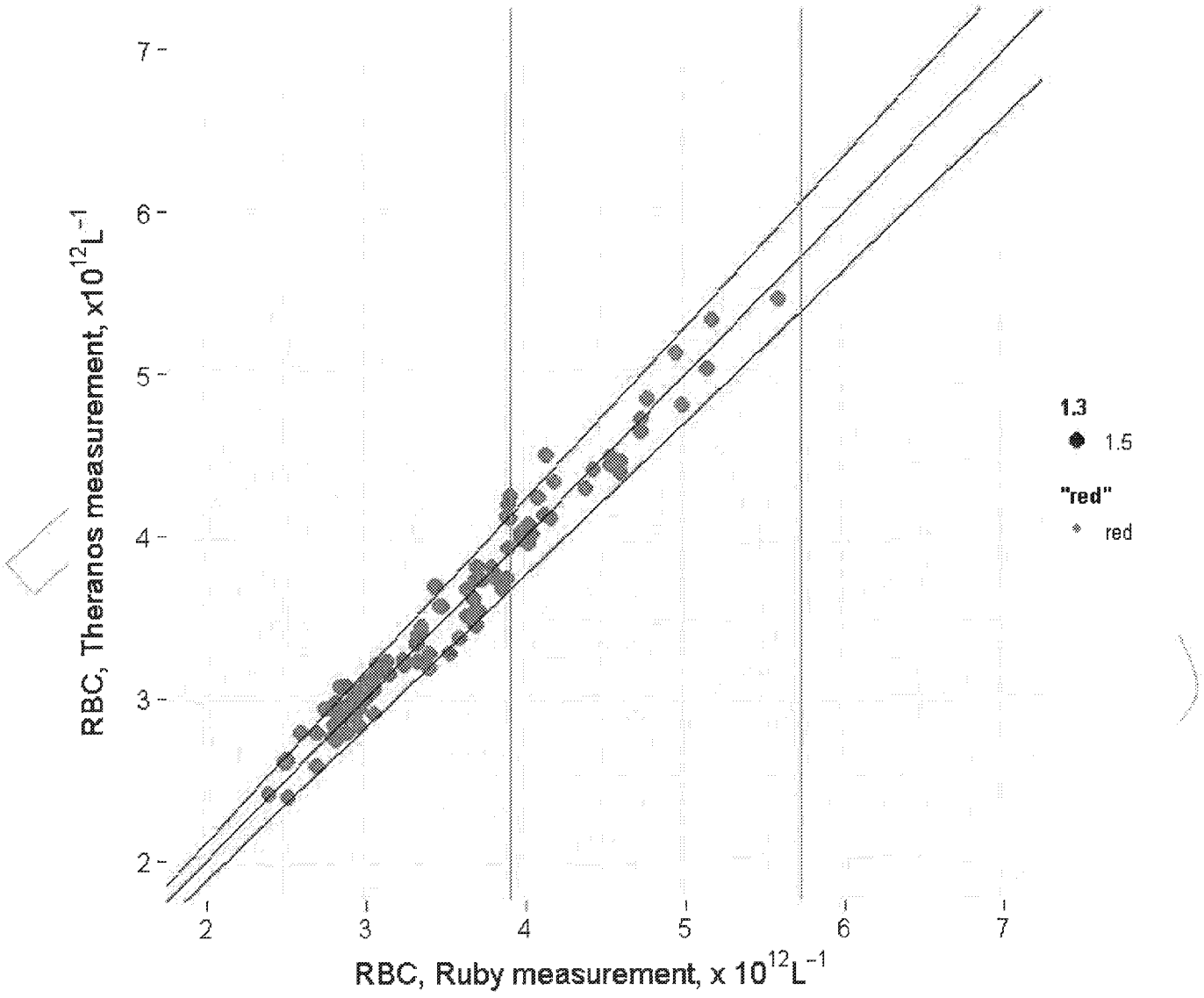

Figure 2 Concordance between Theranos and Ruby measurements for pathological samples obtained from UCSF

Figure 2 demonstrates strong comparability of the Theranos measurement with predicate for these pathological samples. Especially notable is the point plotted in green. This patient was reported to have nucleated RBCs and giant platelets on the UCSF report as well as the predicate used in-house. As seen in the fluorescence scattergrams (Figure 3) below, the separation of bead, RBC and platelet populations is unambiguous for this sample, thus providing confidence on the result.

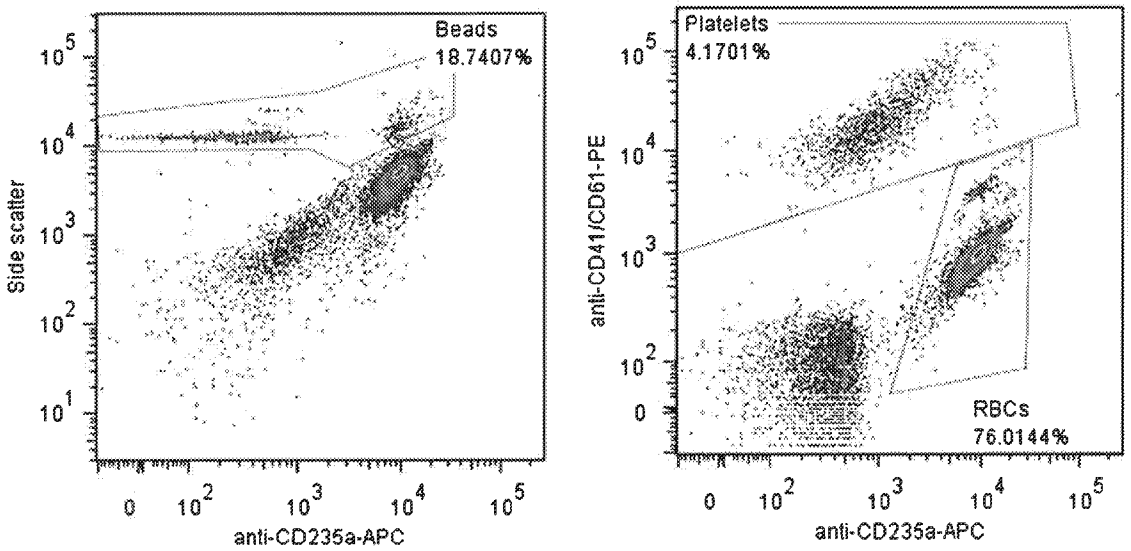

Figure 3Fluorescence scattergrams showing separation between beads and cells (RBC, Plaletes) for pathological sample shown in green in Figure 2

The statistical measures of goodness of fit and bias are provided in the table below.

Parameter	*Value*
Number of data points	113
Slope , [95% C.I.]	0.961, [0.927, 0.994]
Intercept , [95% C.I.]	0.155, [0.035, 0.276]
R^2	0.967
Mean bias (%)	0.64
t-test on mean bias, 95% CI	[-0.04, 1.33]
p-value	0.06

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g. Precision at Medical Decision Limit

There is no medical decision limit for RBC.

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4. Method Comparison

a. Accuracy or Comparability with Predicate

In this section, data showing the comparability or accuracy of the Theranos assay with respect to the predicate assay is presented. The main objective of this exercise is to show that results obtained by Theranos method agree with a CLIA-compliant and FDA-approved hematology analyzer within the total error limits stipulated by CLIA. A secondary, but equally important, objective of this data is to also allow for transference of normal reference range from the predicate to the Theranos method. To increase the confidence in this comparison, pathological samples have also been included in this data set—this widens the range over which comparability is demonstrated.

The figure 4 and 5 below show data for 195 unique samples with 421 total data points. Statistical measures of goodness-of-fit and bias are provided below.

Parameter	*Value*
Number of data points, unique samples	421, 195
Slope , [95% C.I.]	0.999, [0.982, 1.016]
Intercept , [95% C.I.]	-0.004, [-0.082, 0.074]
R^2	0.969
Mean bias (%)	0.211
t-test on mean bias, 95% CI	[0.02, 0.63]
p-value	0.04
Total allowable error, % (from CLIA 1988)	±6
Precision, (%CV)	2.3
Total error, %	0.211 + 2 x 2.3 = 4.81
% points with more than 6% total error	2.9

The total error in measurement with respect to Cell-Dyn Ruby is 4.81%, well within the 6% total allowable error. Accuracy for RBC is within CLIA TAE acceptable limits.

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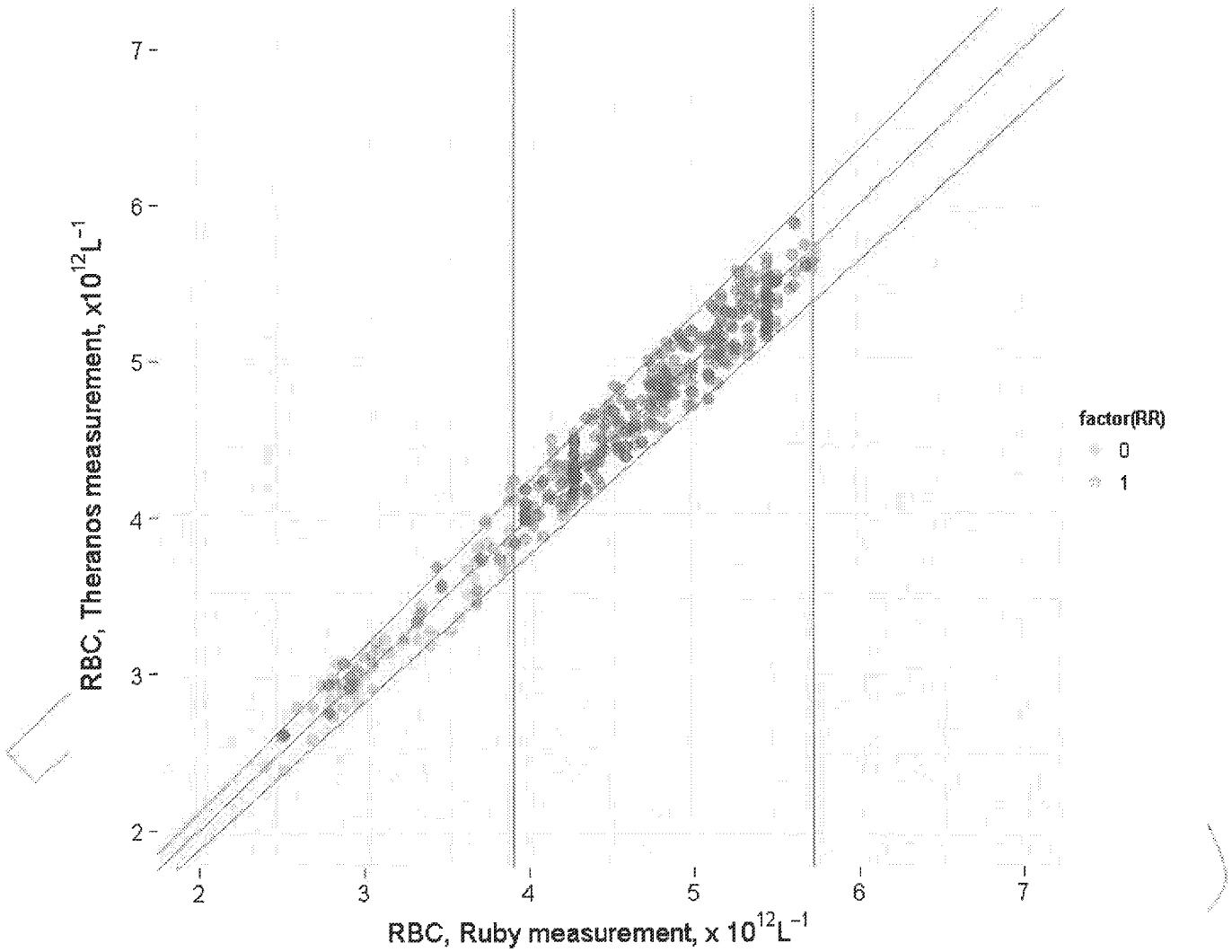

Figure 4 Concordance data showing accuracy of Theranos measurements with respect to CellDyn Ruby for samples in the normal range (Blue) and pathological out of range samples (Red)

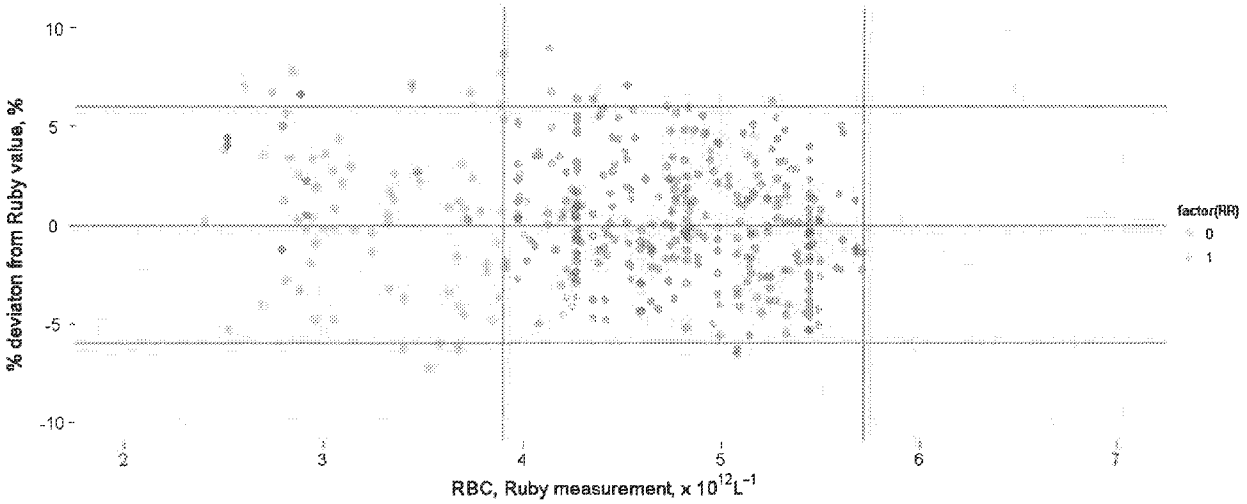

Figure 5 Deviation of Theranos measurement from the Ruby data for in range samples(Blue) and pathological out of normal range samples (Red)

b. Transferance and Verification of Reference Intervals

In CLSI guidance document C28A3, section 10 the determination of reference method by transference is discussed. This strategy allows transfer of reference range from the predicate method to the test method, provided the following criteria are satisfied.

1. The comparability of the analytical system
2. The comparability of the test subject population

Comparability of the test population follows from the fact that these tests are being validated for the same clinical laboratory. Comparability of the analytical system has been established in the foregoing section. The correlation between Theranos method and Abbott Cell-Dyn Ruby is described by:

$$y = 0.999x - 0.004, \qquad r^2 = 0.97$$

The confidence intervals on the slope and the intercept span 1 and 0 respectively, showing the negligible bias of the assay. The reference range for Ruby is [4.06, 5.58], and based on the above equation, for Theranos assay it is:

4.06 transforms to 4.05 x 10^{12} /L

5.58 transforms to 5.57 x 1012 /L.

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This calculation shows that the reference range can be directly transferred. The new reference range of the Theranos RBC assay is therefore [4.05, 5.57].

6. Verification of Pre-analytical methods

a. Verification of Reference Intervals for fingerstick samples

Theranos assays and systems have the ability to process both fingerstick and venous samples. Samples are collected with the Theranos blood collection device which comprises of a capillary channel and an evacuated nanotainer. In order to capture the effect of this collection modality on the performance of the RBC assay, more than 50 nanotainer-samples were analyzed, using the same system as mentioned in earlier sections of this report. The correlation between RBC concentration as measured on Theranos system with fingerstick samples and as measured on the Abbott Cell-Dyn Ruby using a paired venous sample is shown below. Total error (TE) of 5.24% is within the acceptable limit of ± 6%.

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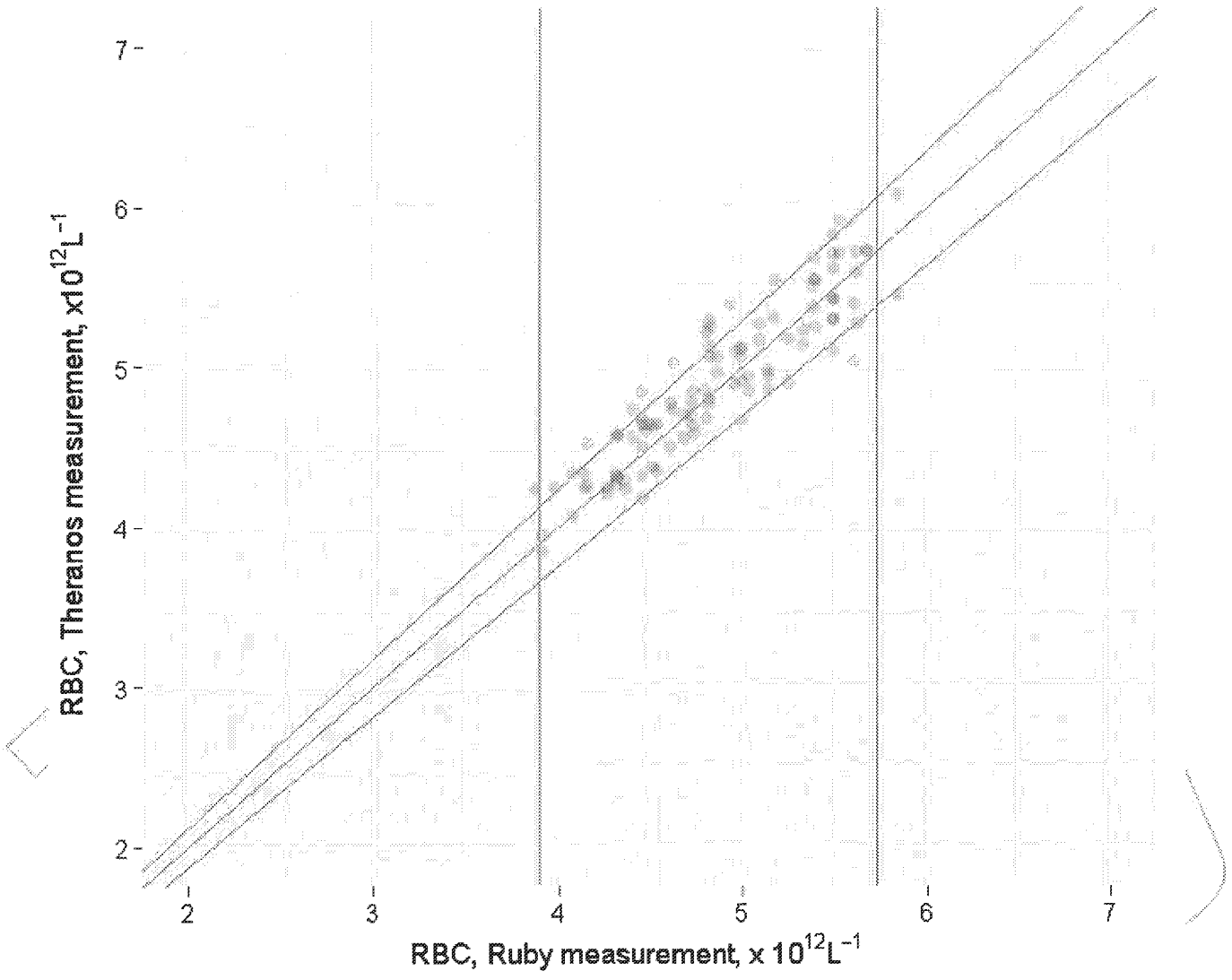
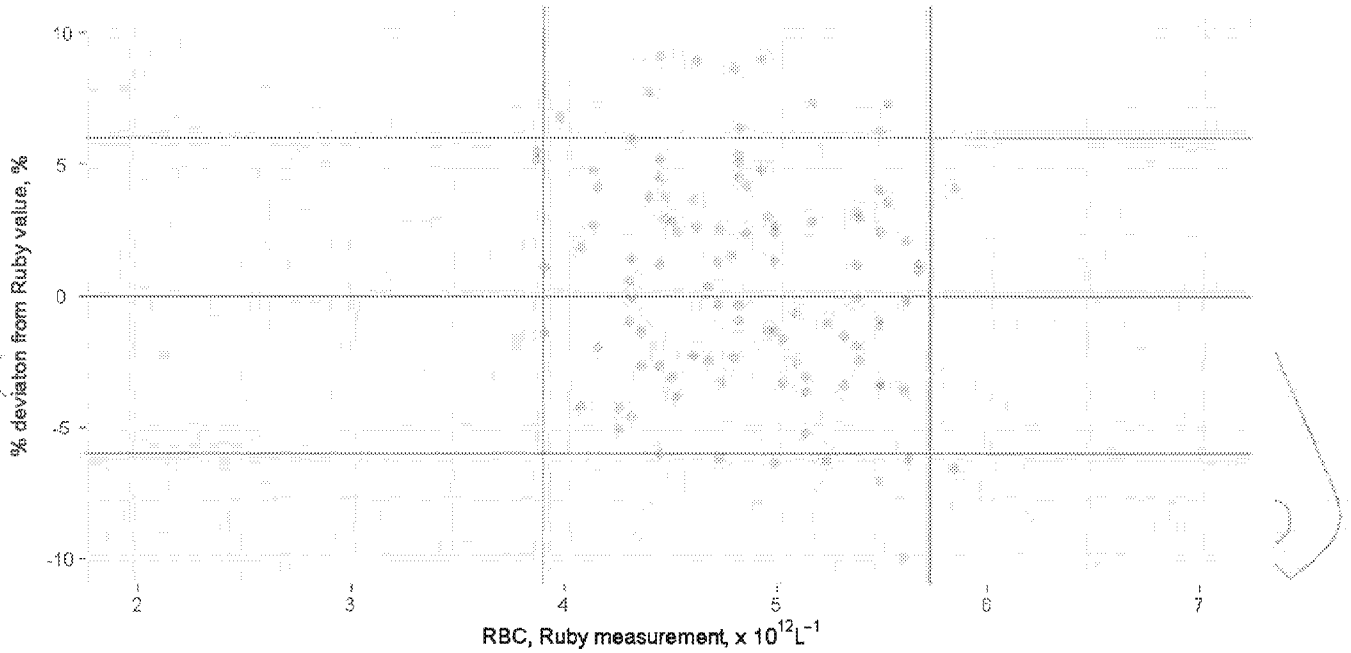

RBC, Theranos measurement, x10^{12}L^{-1}
RBC, Ruby measurement, x 10^{12}L^{-1}
2
3
4
5
6
7

Parameter	*Value*
Number of data points, unique samples	102, 55
Slope , [95% C.I.]	0.93, [0.85, 1.03]
Intercept , [95% C.I.]	0.386, [0.009, 0.76]
R^2	0.85
Mean bias (%)	0.64
t-test on mean bias, 95% CI	[-0.17, 1.44]
p-value	0.1
Total allowable error, % (from CLIA 1988)	±6
Precision, (%CV)	2.3
Total error, %	0.64 + 2 x 2.3 = 5.24



Theranos Platelet Count Assay

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8. Principle
9. Method Characterization
   a. Precision
   b. Establishing the Analytical Measurement Interval or Linearity
   c. Limit of Blank and Carryover
   d. Limit of Detection
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   f. Interference (Pathological samples)
   g. Precision at Medical Decision Limit
10. Method Comparison
   a. Accuracy or Comparability with Predicate
   b. Transferance and Verification of Reference Intervals
11. Verification of Pre-analytical methods
   a. Verification of Reference Intervals for fingerstick samples

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4. Overview

The clinical value of platelet counts has been demonstrated as a fundamental diagnostic and monitoring tool for a broad spectrum of pathologies in numerous studies. In the clinical laboratory, automated flow based devices that use impedance or optical methods for cell detection are commonly used. Platelet counting by automated hematology analyzers has historically been calibrated using manual or indirect methods, such as hemocytometer phase contrast microscopy with an ammonium oxalate diluent or the determination of the erythrocyte to PLT ratio measured with an aperture-impedance counter with a hydrodynamic focused flow stream (indirect platelet counting). A flow cytometry based reference method using ratiometric RBC-PLT counts was published by the International Council for Standardization in Hematology (ICSH) Expert Panel on Cytometry and International Society of Laboratory Hematology Task Force on Platelet Counting (ICSH, 2001).

Known issues with platelet counting include difficulties in discriminating small platelet signals from those of debris and spurious noise, and interference of more numerous RBCs with the PLT count. In addition, spuriously high and low counts are often observed due to sample preparation and pathological conditions. For example, use of ethylenediamine tetra-acetic acid (EDTA) anticoagulation of samples may lead to PLT agglutination by immunoglobulins or PLT satellism or aggregation with leukocytes, leading to low PLT counts. Similarly, fragmented RBCs and cytoplasmic fragments of nucleated cells can lead to spuriously high PLT counts, as these fragments are of a similar size to PLTs and may be erroneously classified as such. Bacteria or lipid droplets have also been erroneously categorized as PLT in optical but not impedance based methods. It can be immediately seen that such confusion will also lead to spurious changes in estimates of platelet volume also. Consequently, the reliability of current automated hematology analyzers for pathological samples in a clinical setting is less than desired.

The Theranos platelet assay has been designed to address many of the issues mentioned above. Fundamentally, platelet specific surface markers were screened and selected. Using the ICSH reference method, it has been shown that potential sources of interference leading to error such as PLT aggregation or PLT-leukocyte adhesion are occasional, fragmented RBCs are rare and congenital platelet disorders are very rare, but that these conditions should be monitored. Glycophorin A, CD235a was also incorporated into the assay to address the interference of RBCs on PLT counts. With an independent marker for RBCs, coincident RBC-PLT events can be identified and monitored to ensure no interference from RBCs on PLT count. RBC-PLT coincident events accounts for ~10% of all PLT counts and optical light scattering methods currently do not take this population into account.

In this document, a flow cytometry based counting assay is validated against Abbott Cell-Dyn Ruby, an automated hematology analyzer.

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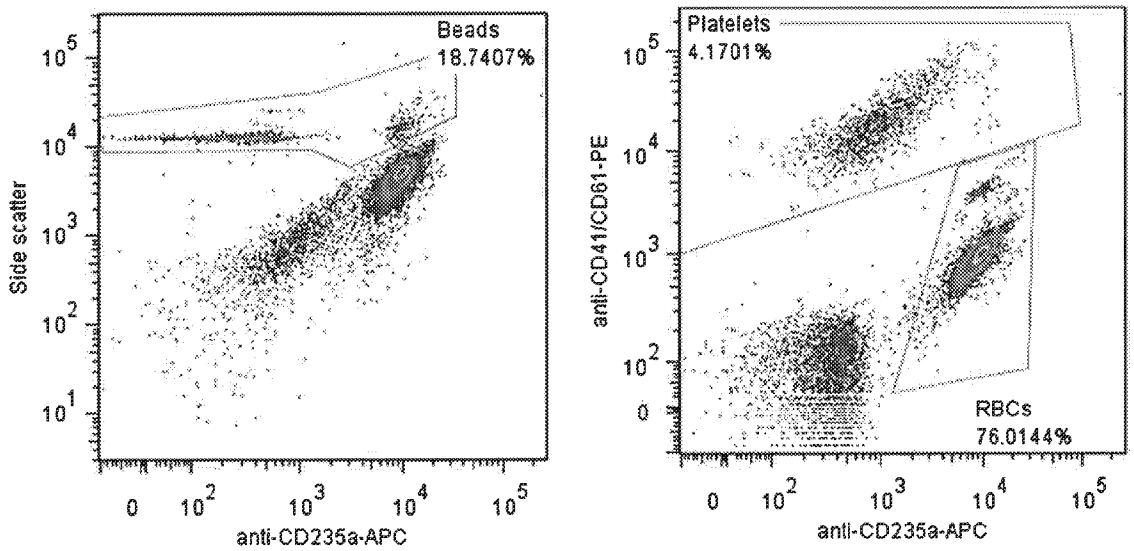
5. Principle

In this assay, platelets (PLT) are identified by fluorescently conjugated antibodies that recognize the antigens CD41 and CD61 (glycoproteins integrin alphaIIb and integrin betaIIIa), which are expressed on the surface of platelets.

To determine the number of platelets per unit volume of whole blood, a known number of polystyrene microbeads are added to the sample to be used as a counting standard.

Thus, in this assay, whole blood is added to a solution containing fluorescently conjugated anti-CD41 and anti-CD61 antibodies and polystyrene microbeads, incubated to allow the antibodies to bind to the platelets, then fixed and analyzed on a flow cytometer (BD Biosciences LSRFortessa, BD Biosciences Accuri, or Millipore Guava). The fluorescence intensity and light scatter information is captured in data files generated by the flow cytometer. This data is analyzed in multiple dimensions to allow for unambiguous gating of the platelet events and the bead events (see Figure below).



The format of the assay is in a multiwell microtiter plate so that sample preparation can be carried out on 24 or more samples at a time. The platelet count is calculated by determining the number of CD41/CD61-positive events and the number of microbeads, and using the following formula to calculate the platelet concentration present in the whole blood that was tested.

$$Platelet\ count\ (cells/L) = (\frac{CD41/CD61\ positive\ events}{bead\ events})(number\ of\ beads\ in\ reagent)$$

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6. Method Characterization

h. Precision:

CLSI standard EP05-A2 defines precision as the closeness of agreement between independent test/measurement results obtained under stipulated conditions. The term stipulated conditions encompasses a wide variety of contexts encountered in the process of clinical analysis. For the purpose of this validation study, precision was measured and characterized in the following contexts:

- within plate (or run) precision
- across plate (or run) precision
- within day precision
- between day precision

The main objective behind characterization of precision under the above conditions is to demonstrate that this method is robust to the different sources of variation inherent in the analytical method.

5. Within plate (or run) precision: Sixteen replicates of the same sample were analyzed on an assay plate. The coefficient of variation across these replicates characterizes the within run precision for this method.

Platelets	*plate 1*	*plate 2*	*plate 3*
Mean of 16 replicates (x10^9 cells/L)	326	325	323
CV (%)	4.8	3.6	3.4
Acceptable CV (%)	< 12.5	< 12.5	< 12.5
Pass/Fail	Pass	Pass	Pass

6. Across plate (or run) precision: The foregoing data also allows us to characterize the across run precision, as the three plates had the same sample across them. Across all 16 x 3 = 48 replicates of this sample, the coefficient of variation was 3.5%. Further, in a separate study, three separate samples were analyzed in replicates of ≥ 31 each to establish the standard deviation of the measurement. The results from this study are included in the table below.

Date	*Donor*	*Replicates*	*Recovery*	*CV*	*Acceptable CV*	*Pass/Fail*
20130814	307	48	102.9	3.5	< 12.5	Pass
20130820	244	32	99.8	2.56	< 12.5	Pass
20130823	283	31	103.5	3.89	< 12.5	Pass

7. Within day precision and between day precision: For enumeration assays such as this Platelet assay, the dependence of imprecision on analyte concentration is determined by the number of particles enumerated in a fixed dilution and counting scheme. At lower concentrations, fewer particles are enumerated and the imprecision

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in the point estimate of particle concentration increases (governed by Poisson distribution). However, for Platelet the normal range is narrow enough so that for all samples that fall in the normal range a significant number of particles is enumerated. Hence the concentration dependence of impression can be ignored. This argument is presented here to lay the basis for using sample recovery across different donors and different days as a way to characterize within and between day precision. In the table below, several plates run over several days have been combined and compared based on recovery. The variation in within-day precision can be clearly seen. The last column shows coefficient of variation calculated by aggregating all data points over different days.

Date	*Mean recovery (%)*	*CV (%)*	*Number of data points*
2013-08-20	107.4	3.9	32
2013-08-21	103.9	5.2	15
2013-08-22	100.7	7.4	62
2013-08-23	93.8	5.1	44
2013-08-25	92.3	7.6	8
2013-08-26	102.1	4.5	22
2013-08-27	96.3	12.1	32
2013-08-29	95.0	4.7	7
2013-08-30	95.7	7.2	31
2013-09-01	94.0	5.5	17
2013-09-02	105.1	8.0	19
2013-09-03	105.5	10.8	41
2013-09-05	104.9	8.6	32
Across all days	**100.0**	**9.3**	**362**
Acceptable CV (%)	**< 12.5**	**< 12.5**	**< 12.5**
Pass/Fail	**Pass**	**Pass**	**Pass**

i. Establishing the Analytical Measurement Interval or Linearity

CLSI guidance document H26AE defines the analytical measurement interval or analytical measurement range as the range of analytical values that a method can directly measure on the specimen without any dilution, concentration, or other pretreatment not part of the usual assay process. The aim of this part of the validation program was to establish an analytical measurement range significantly wider than the typical clinically reportable interval. In effect, this implies that the said method will provide sensible results, without dilution, concentration or other pretreatment for any sample which the laboratory wishes to analyze. To this end, fresh whole blood samples were manipulated to yield a range of PLT concentrations from 10 to 1800 x 10^9 cells/L. This range

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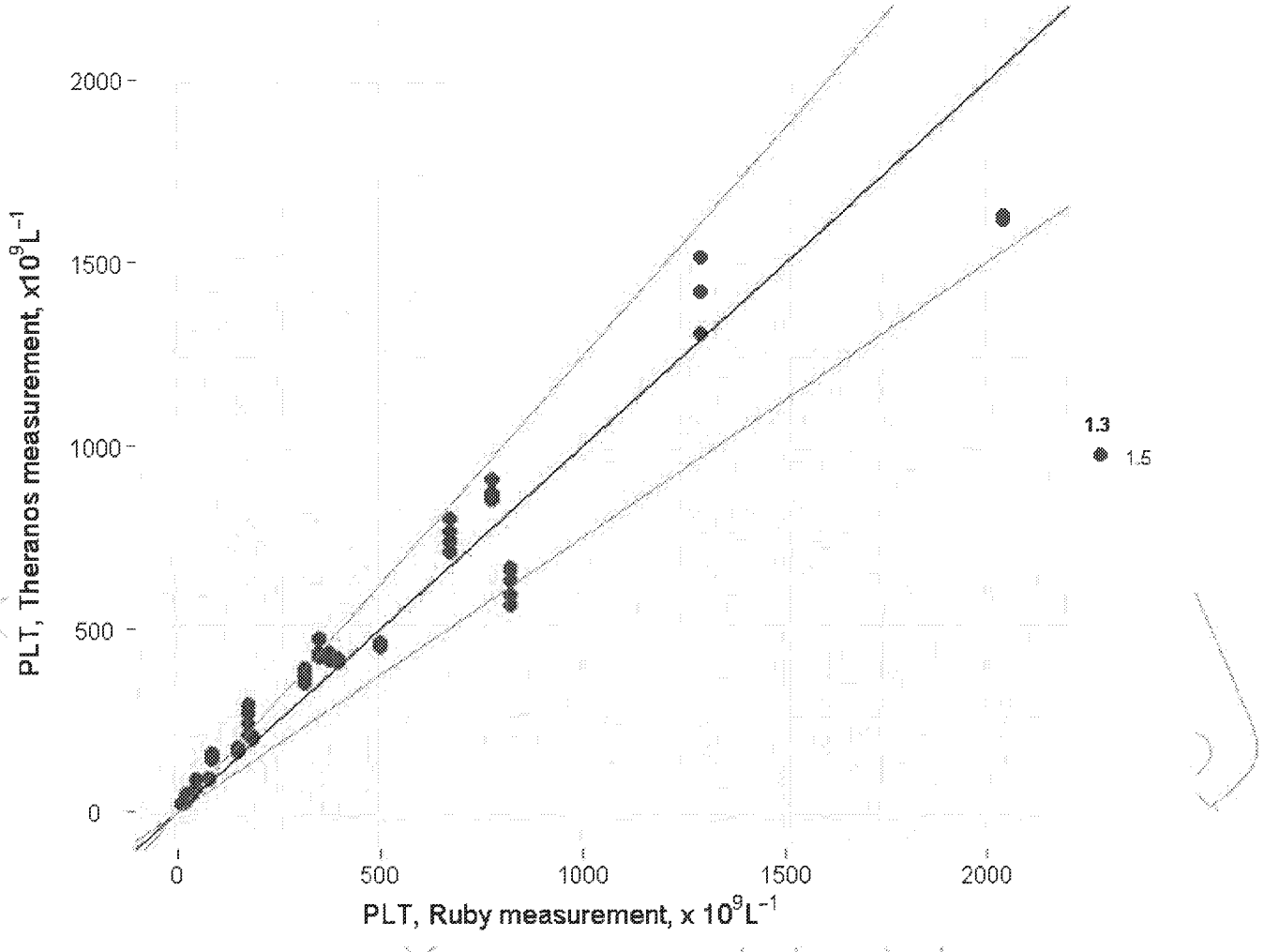
is significantly wider than any expected physiological range. These samples were processed in the usual way and analyzed for PLT concentration. Graphical representation and regression statistics for this dataset are included below. The goodness of fit establishes the "linearity" or the analytical measurement interval for this assay over 10 to 1800 x 10^9 cells/L.



Parameter	*Value*
Slope , [95% C.I.]	1.045, [0.992, 1.106]
Intercept , [95% C.I.]	-32.83, [-64.76, -0.887]
R^2	0.946

j. Limit of blank (LoB) and carryover

Since the Theranos assay system uses a flow cytometer as the analytical device for enumeration of red blood cells, carryover from one sample to the next is a distinct possibility. In spite of including a wash step between two consecutive samples, a small finite amount of carryover is unavoidable. The impact of carryover is characterized as the change in the measured value of a 'low' sample when it is run subsequent to a 'high' sample. This study was performed together with characterization of the limit of blank because the effective limit of blank strongly depends upon carryover. For these studies, 8 blank samples were run consecutively and analyzed to get the limit of blank with no carryover considerations. Next, alternate high (PLT ~ 229 & 292 x 10^9/L) and blank samples were run to quantify the limit of blank with carryover.

Parameter	*Value*	*Unit*
Limit of blank, no carryover	0.015 ± 0.029	x 10^9/L
Limit of blank, with carryover	1.15 ± 0.25	x 10^9/L
Limit of blank, with carryover as percent of concentration of prior sample	0.44 ± 0.096	%

It is worth noting here that one of the reasons the limit of blank and carryover are significantly lower in the Theranos assay system as compared to predicate devices (where the norm is >1%, typically 1.5%) because of the specific epitope-based cell identification method used here. Due to epitope based identification, for a particle to be classified as a red cell, it must stain positive for CD41/61-PE and have side scatter in the correct range. Spurious events that satisfy these conditions are much fewer—hence the negligible limit of blank. Carryover is low due to extensive washes run after each sample run.

k. Limit of detection (LoD)

CLSI guidance document EP17-A2 defines the limit of detection (LoD) as the measurand quantitity value, obtained by a given measurement procedure, for which the probability of falsely claiming the absence of a measurand in a material is β, given a probability α of falsely claiming its presence. For the purpose of this validation program, α and β were selected to be 0.05. Guidelines from section 5.3.3 were used for designing the experiments and analyzing data. Briefly, three low level samples were contrived from fresh whole blood at concentrations ranging from 1 to 10 x10^9/L. These samples were analyzed in quadruplicate along with blanks. From these data:

LoB = 0.015 (x10^9 /L)

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J = number of low level samples run = 3 (consider only the lowest here)
L = number of results from these J samples = 12 (quadruplicate)
SD_L = standard deviation of all the L low level samples

$$LoD = LoB + SD_L\left(\frac{1.645}{1-\frac{1}{4(L-J)}}\right) = 0.374\ x\ 10^9\ cells/L$$

The limit of detection therefore is significantly lower than expected value for any physiological sample.

l. Limit of Quantification (LoQ)

CLSI guidance document EP17A2E defines the limit of quantification (LoQ) as the lowest amount of measurand in a material that can be quantitatively determined with stated accuracy under stated experimental conditions. Accuracy goals therefore need to be stated *a priori*. Then trial value of LoQ is picked based on the desired value the laboratory wants to claim. Based on the analytical measuring interval, a value of 10 x 10^3/uL was selected as the target LoQ.

Accuracy goal was stated using the Westgard model:

$$TE = |bias| + 2\,SD$$

where, TE = the total error, bias is calculated as difference of measured value from the reference value of the sample at LoQ and SD is the standard deviation of measured values. The total error goal for this assay was defined to be 25% of the reference value of the LoQ sample.

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The data and calculations tabulated below show that a sample at 10 x 10^9/L can be measured with a total error of less than 25%.

PLT, measured (x10^9/L)	*Reference value (x10^9/L)*	*Absolute bias (x10^9/L)*
9.2	9.7	0.4
9.8	9.7	0.2
9.2	9.7	0.4
10.3	9.7	0.6
11.2	9.7	1.6
9.8	9.7	0.1
8.8	9.7	0.9
8.8	9.7	0.9
9.2	9.7	0.4
9.8	9.7	0.2
9.2	9.7	0.4
10.3	9.7	0.6
SD = 0.83		Mean = 0.64
TE = 0.64 + 2 x 0.83 = 2.3 = 23.7% of Ref value		

m. Interference (pathological samples)

CLSI guidance document H26A2E defines interference as an artifactual increase or decrease in apparent concentration or intensity of a measurand due to the presence of a substance that reacts nonspecifically with either the detecting reagent or the signal itself. In traditional hematology analyzers where platelets are detected based on their size or light-scattering properties, presence of similar sized particles is the primary reason for interference. In the Theranos assay, platelets are detected based on their light scattering properties but identified as platelets based on their positive staining with CD41/61. Consequently, interferants such as RBC fragments, microcytes etc are not expected to have an impact on the assay. One major source of interference is the possibility that the antibody used for detecting platelets in this assay does not recognize the integrin complex on a certain sample. In more than 1000 samples that have been analyzed by our laboratory over the last 2 years during which this assay was under development, not a single instance of absence of CD41/61 staining has been observed.

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Pathological samples collected in the morning were sourced from UCSF laboratories and analyzed on the same day. The following conditions were reported in the UCSF laboratory reports.

Condition	*Number of samples*
Thrombocytopenia (PLT<150 x 10^9/L)	41
Thrombocytosis (PLT > 450 x 10^9/L)	58
Microcytosis (MCV < 80 fL)	9

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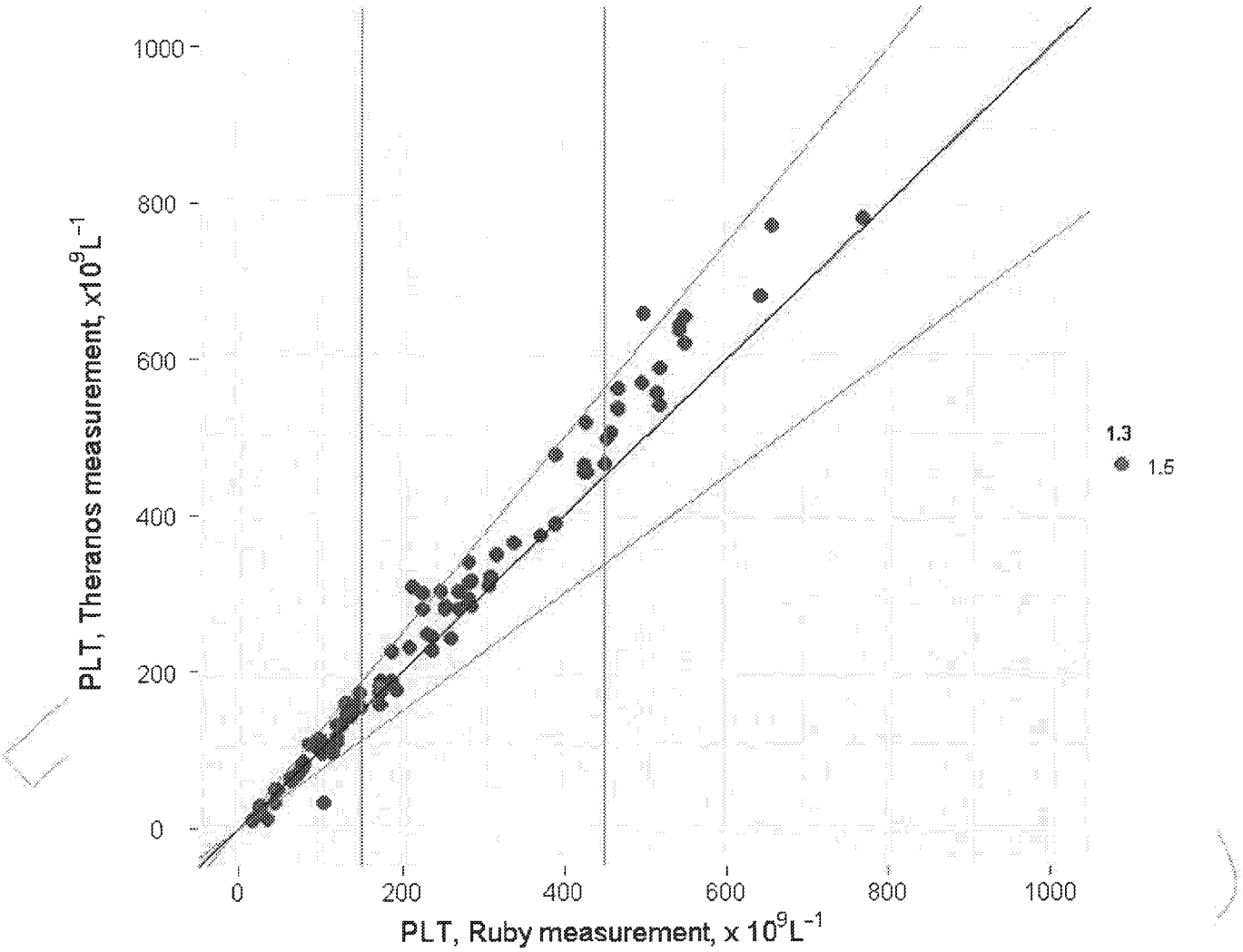
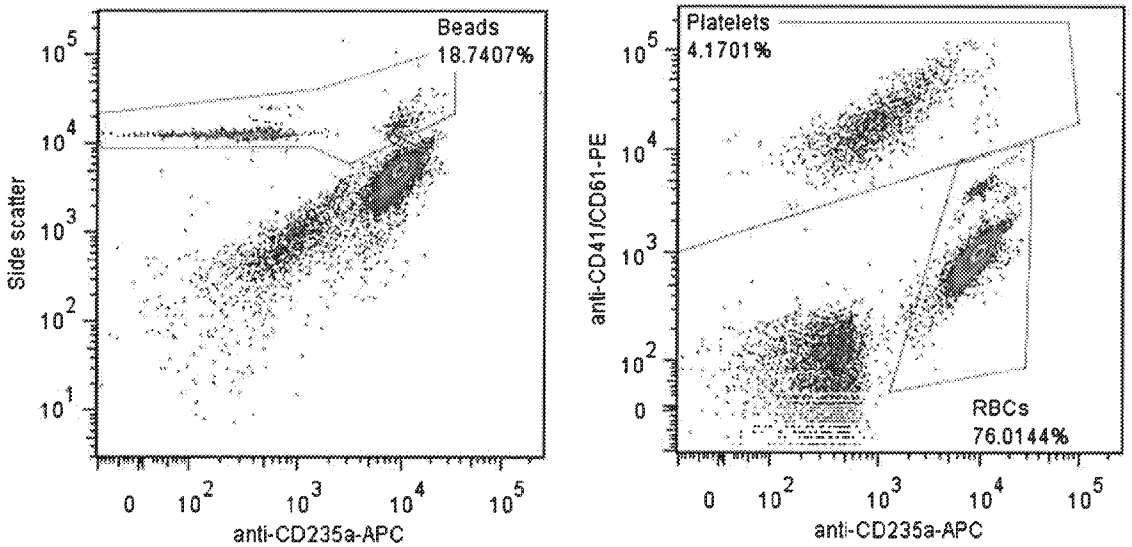


The figure demonstrates strong comparability of the Theranos measurement with predicate for these pathological samples. Especially notable is the point plotted in green. This patient was reported to have nucleated RBCs and giant platelets on the UCSF report as well as the predicate used in-house. As seen in the fluorescence scattergrams below, the separation of bead, RBC and platelet populations is unambiguous for this sample, thus providing confidence on the result.



The statistical measures of goodness of fit and bias are provided in the table below.

Parameter	*Value*
Number of data points	113
Slope, [95% C.I.]	1.113, [1.11,1.169]
Intercept , [95% C.I.]	-14.28, [-23.16, -5.4]
R^2	0.981
Mean bias (%)	3.88
t-test on mean bias, 95% CI	[0.93, 6.82]
p-value	0.01

n. Precision at Medical Decision Limit

CLSI guidance document H26A2E, section 5.9.2 recommends that the precision of an assay at the medical decision limit be characterized during validation. For platelets, the key medical decision limit is in the range of 0-50 x 10^9 /L, where transfusion decisions are made. To this end, platelet samples in the middle of this range (26 x 10^9 /L) were contrived and assayed for precision by running 24 consecutive replicates. For further evidence of the suitability of the assay for thrombocytopenic

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samples, the reader is referred to section f where data for more than 40 such samples is presented. Total Error at MDL is 15.8%, which is within the TAE of 25%. Precision at the MDL is acceptable.

Parameter	*Value*
Number of data points	24
Nominal value (x 10^9/L)	26
Mean of 24 replicates (x 10^9/L)	27.86
95% CI (x 10^9/L)	[27.3, 28.4]
p-value	$<2 \times 10^{-16}$
Mean bias (%)	7.15
Precision (%CV)	4.34
Total Error at MDL (%)	7.15 + 2 x 4.34 = 15.8

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8. Method Comparison

b. Accuracy or Comparability with Predicate

In this section, data showing the comparability or accuracy of the Theranos assay with respect to the predicate assay is presented. The main objective of this exercise is to show that results obtained by Theranos method agree with a CLIA-compliant and FDA-approved hematology analyzer within the total error limits stipulated by CLIA. A secondary, but equally important, objective of this data is to also allow for transference of normal reference range from the predicate to the Theranos method. To increase the confidence in this comparison, pathological samples have also been included in this data set—this widens the range over which comparability is demonstrated.

The figure below shows data for 195 unique samples with 421 total data points. Statistical measures of goodness-of-fit and bias are provided below.

Parameter	*Value*
Number of data points, unique samples	421, 195
Slope , [95% C.I.]	1.05, [1.024, 1.078]
Intercept , [95% C.I.]	-13.41, [-21.3, -5.52]
R^2	0.93
Mean bias (%)	-0.42
t-test on mean bias, 95% CI	[-1.49, 0.64]
p-value	0.04
Total allowable error, % (from CLIA 1988)	12.5
Precision, (%CV)	4.5
Total error, %	0.42 + 2 x 4.5 = 9.42

The total error in measurement with respect to Cell-Dyn Ruby is 9.42%, well within the 25% total allowable error.

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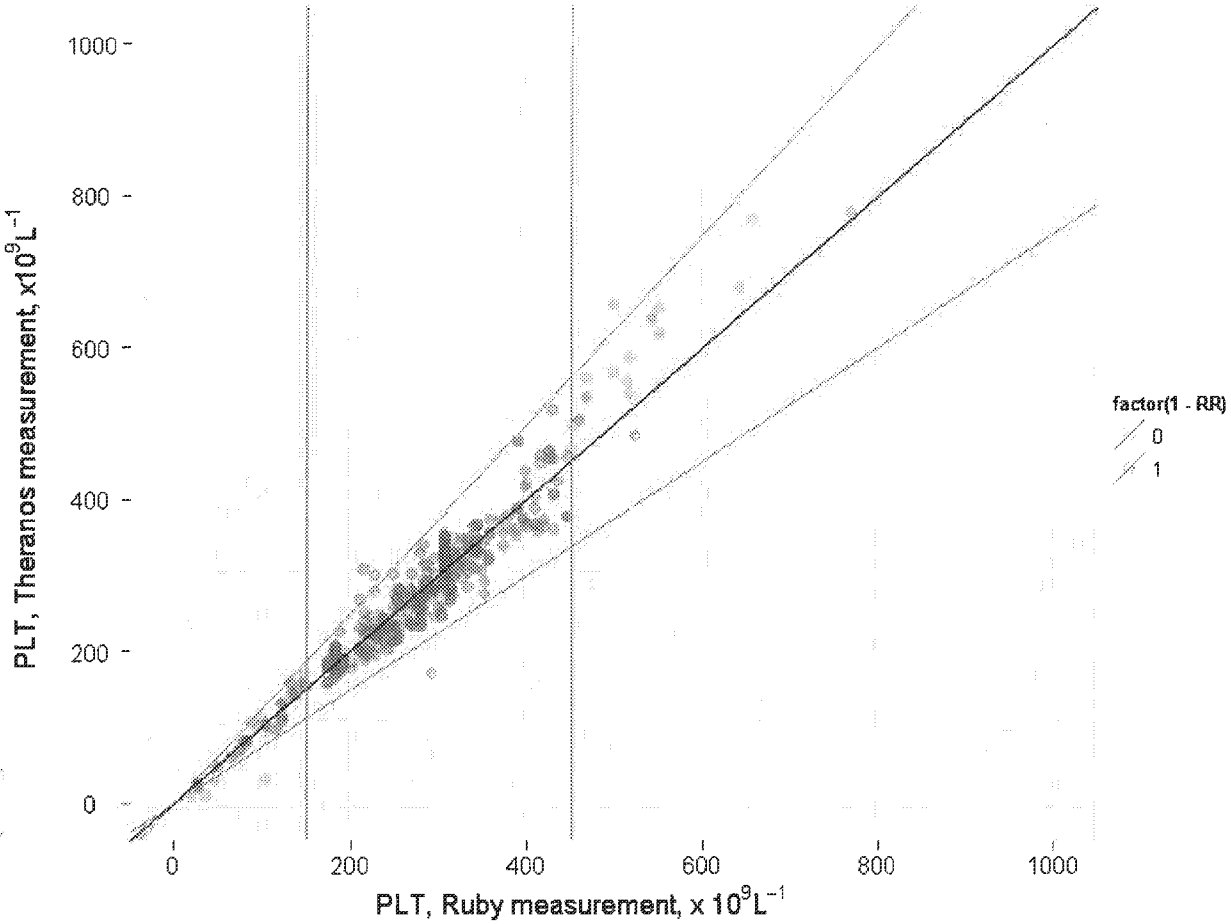

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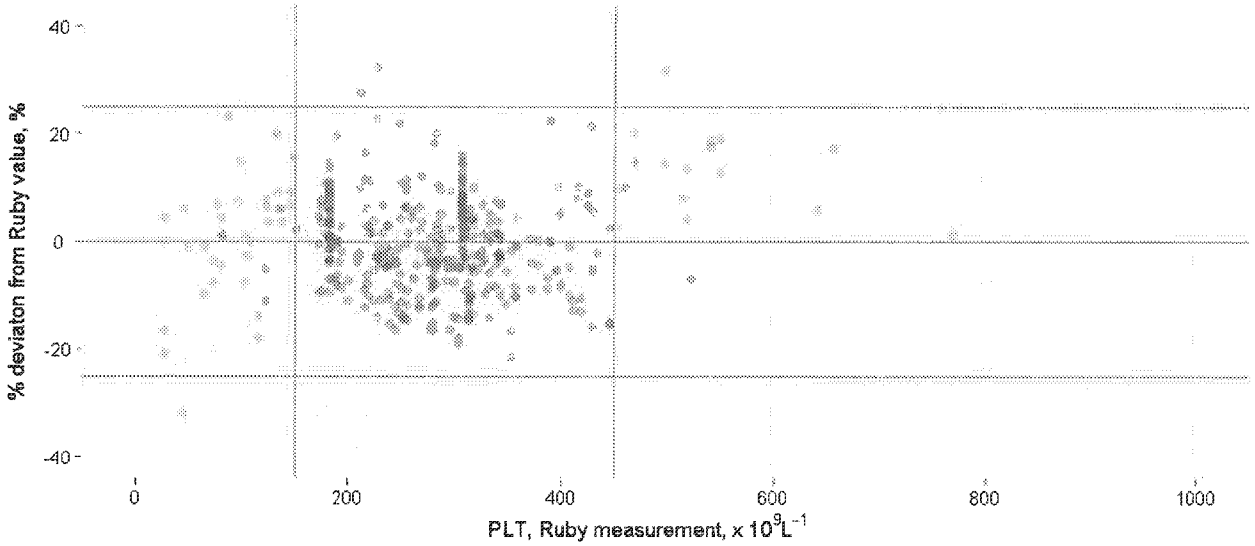

b. Transferance and Verification of Reference Intervals

In CLSI guidance document C28A3, section 10 the determination of reference method by transference is discussed. This strategy allows transfer of reference range from the predicate method to the test method, provided the following criteria are satisfied.

3. The comparability of the analytical system
4. The comparability of the test subject population

Comparability of the test population follows from the fact that these tests are being validated for the same clinical laboratory. Comparability of the analytical system has been established in the foregoing section. The correlation between Theranos method and Abbott Cell-Dyn Ruby is described by:

$$y = 1.051x - 13.413, \qquad r^2 = 0.93$$

The confidence intervals on the slope and the intercept do not span 1 and 0 respectively, thus showing the small bias of the assay. The reference range for Ruby is [155, 366], and based on the above equation, for Theranos assay it is:
155 transforms to 150 x 10^9 /L
366 transforms to 371 x 10^9 /L.

This calculation shows that the reference range can be directly transferred. The new reference range of the Theranos PLT assay is therefore [150,371] x 10^9/L.

12. Verification of Pre-analytical methods

a. Verification of Reference Intervals for fingerstick samples

Theranos assays and systems have the ability to process both fingerstick and venous samples. Samples are collected with the Theranos blood collection device which comprises of a capillary channel and an evacuated nanotainer. In order to capture the effect of this collection modality on the performance of the platelet assay, more than 50 nanotainer-samples were analyzed, using the same system as mentioned in earlier sections of this report. The correlation between platelet concentration as measured on Theranos system with fingerstick samples and as measured on the Abbott Cell-Dyn Ruby using a paired venous sample is shown below.

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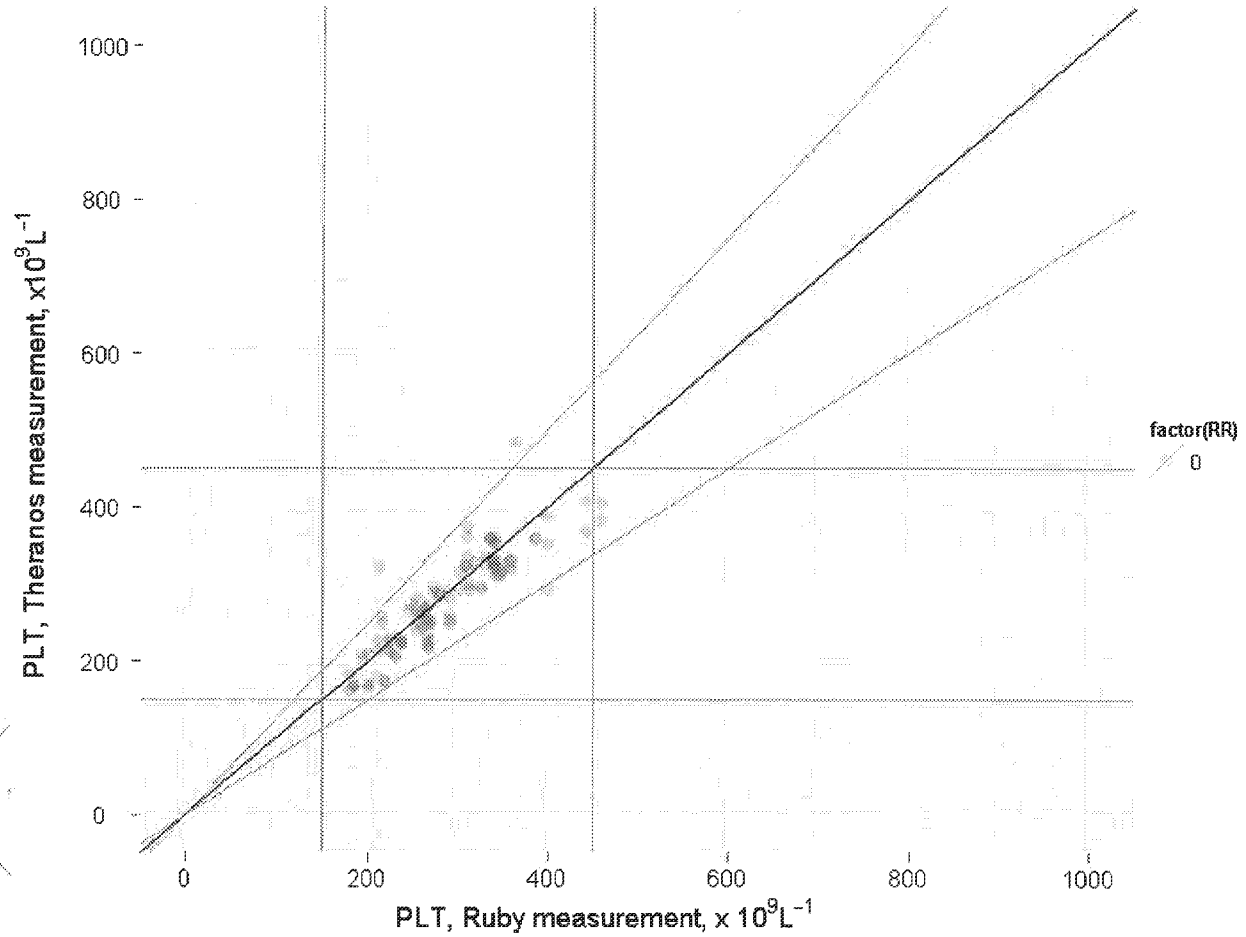

Parameter	Value
Number of data points, unique samples	102, 55
Slope , [95% C.I.]	0.88, [0.8, 0.95]
Intercept , [95% C.I.]	24.36, [1.99, 46.74]
R^2	0.85
Mean bias (%)	-2.73
t-test on mean bias, 95% CI	[-4.9, -0.55]
p-value	0.01
Total allowable error, % (from CLIA 1988)	±25
Precision, (%CV)	4.5

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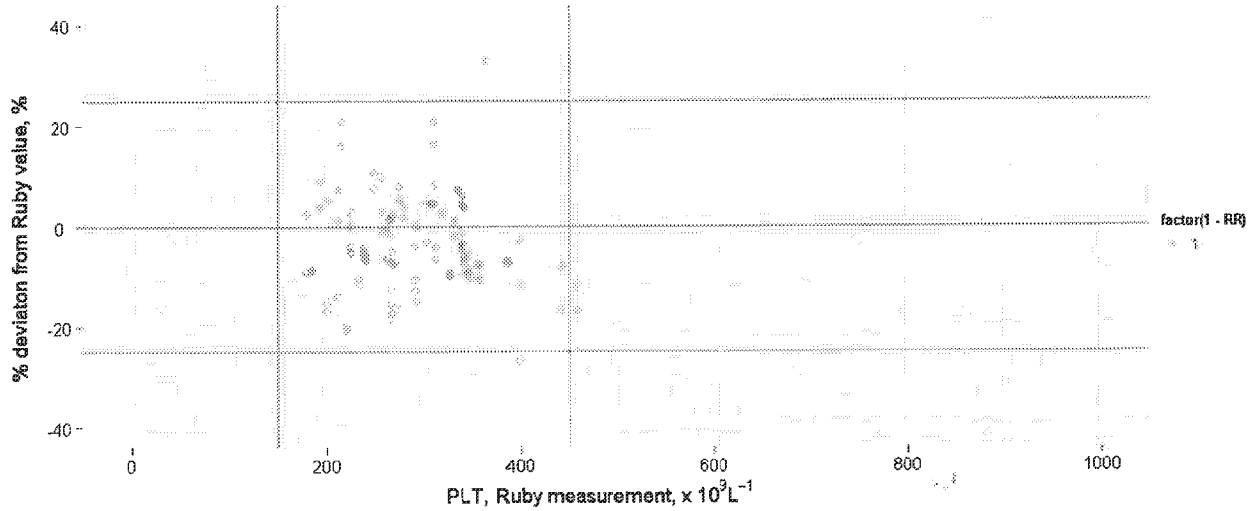
Total error, %	2.73 + 2 x 4.5 = 11.73
% points with more than 25% total error	2.9



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Theranos Leukocyte Differential Assay

13. Overview
14. Principle
15. Method Characterization
    a. Precision
    b. Establishing the Analytical Measurement Interval or Linearity
    c. Limit of Blank and Carryover
    d. Limit of Detection
    e. Limit of Quantification
    f. Interference (Pathological samples)
    g. Precision at Medical Decision Limit
16. Method Comparison
    a. Accuracy or Comparability with Predicate
    b. Transferance and Verification of Reference Intervals
17. Verification of Pre-analytical methods
    a. Verification of Reference Intervals for fingerstick samples

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7. Overview

The clinical value of leukocyte count and differential has been demonstrated in numerous studies. Current state of the art is dominated by class of devices called Automated Hematology Analyzers which classify leukocytes based on their physical properties such as size, granularity, absorbance etc. which have been historically validated for normal samples. This, combined with a coulter-principle based counting mechanism allows for rapid processing of samples, often providing results in minutes. However, in practice, a significant fraction of samples are abnormal (50% for hospital labs and 25% for independent labs) and are flagged by automated analyzers[1-2]. This prompts a reflex to a reference counting method, which in almost all cases is manual blood smear and slide review. Manual slide reviews allow identification of rare and abnormal cells via morphological analysis; but they are slow, expensive, require trained operators and are often inaccurate and insensitive (due to the fact that only 100-200 cells are counted per sample). Consequently, the effective speed, and hence the clinical value, of a current automated CBCs is seriously compromised. The need for a cheaper, faster and versatile reference CBC has existed for many years.

The Theranos CBC assay is designed to combine the rapidity and sensitivity of an automated method with the robustness and versatility of the manual blood smear—i.e. a rapid reference CBC. Instead of classifying cells based on their physical properties (size, absorbance, granularity) we classify cell types based on expression of specific epitopes well established in the literature. For example, neutrophils as CD16/CD45[4-7] positive, monocytes as CD14/CD45[4-7] positive and so on. Based on reports in literature[1,4], we estimate that Theranos CBC will be able to reduce the 'reflex to manual slide review' rate by about 85%.

In this document, a flow cytometry based counting assay is validated against Abbott Cell-Dyn Ruby, an automated hematology analyzer.

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8. Principle

This assay is designed to enumerate and classify white blood cells (WBCs; leukocytes) in whole blood. The assay reports the total count of WBCs per unit volume of whole blood as well as the proportions of neutrophils, eosinophils, basophils, monocytes and lymphocytes in the total leukocyte population.

In this assay, WBCs are identified by a fluorescent dye that binds to the DNA of nucleated cells (DRAQ5). Subclasses of WBCs (neutrophils, lymphocytes, monocytes, eosinophils, and basophils) are further identified by labeling with a cocktail of antibodies that recognize different cell types. Red blood cells, which outnumber WBCs by 1000 to 1, are lysed using a buffer containing a detergent. The detergent (saponin) introduces holes in the membranes of all cells, which releases the hemoglobin from the RBCs and prevents them from obscuring the WBCs during analysis. WBCs are also fixed using formaldehyde during this step, which prevents any further changes to their properties prior to analysis.

The antibodies used to identify subclasses of WBCs are: CD14 (monocytes), CD16 (neutrophils and a subset of lymphocytes), CD123 (basophils), and CD45 (labels all WBCs but lymphocytes have higher expression than the other subclasses).

To determine the number of WBCs per unit volume of whole blood, a known number of polystyrene microbeads are added to the sample to be used as a counting standard.

Thus, in this assay, whole blood is added to a solution containing a fluorescent DNA dye (DRAQ5), fluorescently conjugated antibodies which recognize subclasses of WBCs, and polystyrene microbeads. The mixture is incubated to allow the antibodies to bind to the cells. The saponin-based lysis buffer containing formaldehyde is then added to the sample to lyse the red blood cells and fix the WBCs. The sample is then analyzed on a flow cytometer (BD Biosciences LSRFortessa, BD Biosciences Accuri, or Millipore Guava). The fluorescence intensity and light scatter information is captured in data files generated by the flow cytometer. This data is analyzed in multiple dimensions to allow for unambiguous gating of the WBC events and the bead events (See Figure below), as well as to distinguish between the 5 subclasses of WBCs.

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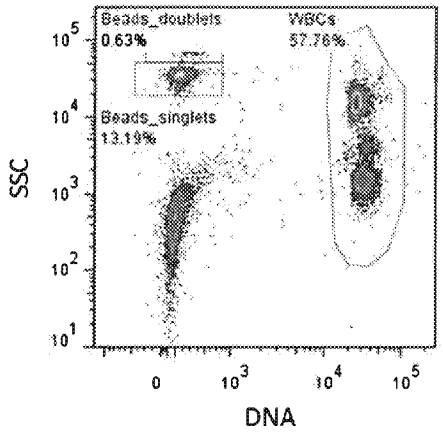

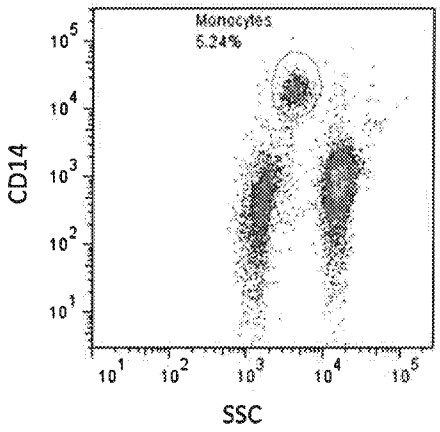

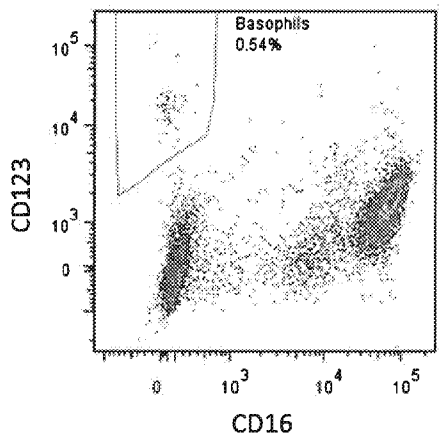

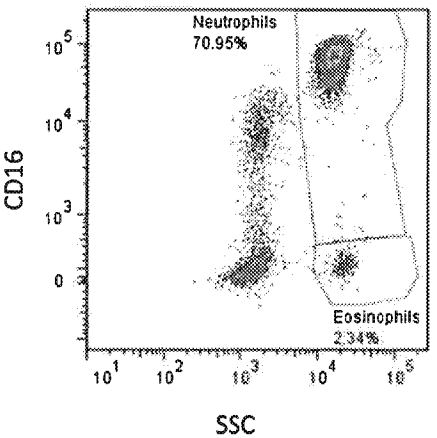

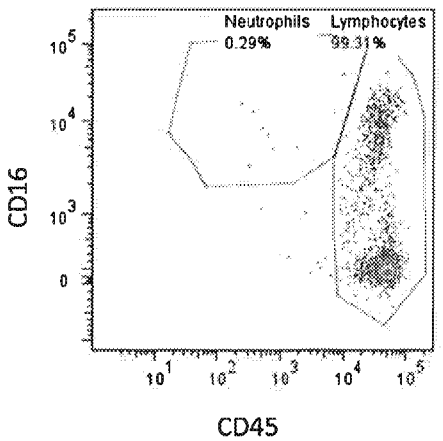

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The format of the assay is in a multiwell microtiter plate so that sample preparation can be carried out on 24 or more samples at a time. The WBC count is calculated by determining the number of DRAQ5-positive events and the number of microbeads, and using the following formula to calculate the WBC concentration present in the whole blood that was tested.

$$WBC\ count\ (cells/L) = \left(\frac{DRAQ5\ positive\ events}{bead\ events}\right)(number\ of\ beads\ in\ reagent)$$

The differential is then determined by counting how many of the WBCs fall into each subclass as shown in the Figure above. Neutrophils are identified as being bright for CD16 and having high side scatter. Lymphocytes are bright in CD45 and have low side scatter. Monocytes are positive for CD14 and have intermediate side scatter. Eosinophils have high side scatter and are CD16-negative. Basophils are bright for CD123, negative for CD16, and have intermediate side scatter.

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9. Method Characterization

o. Precision:

CLSI standard EP05-A2 defines precision as the closeness of agreement between independent test/measurement results obtained under stipulated conditions. The term stipulated conditions encompasses a wide variety of contexts encountered in the process of clinical analysis. For the purpose of this validation study, precision was measured and characterized in the following contexts:

- within plate (or run) precision
- across plate (or run) precision
- within day precision
- between day precision

The main objective behind characterization of precision under the above conditions is to demonstrate that this method is robust to the different sources of variation inherent in the analytical method.

9. Within plate (or run) precision: Sixteen replicates of the same sample were analyzed on an assay plate. The coefficient of variation across these replicates characterizes the within run precision for this method.

WBC	*plate 1*	*plate 2*
Mean of 16 replicates (x10^9 cells/L)	6.56	6.7
CV (%)	1.79	3.24
Acceptable CV (%)	< 7	< 7
Pass/Fail	Pass	Pass

10. Across plate (or run) precision: The foregoing data also allows us to characterize the across run precision, as the three plates had the same sample across them. Across all 16 x 2 = 32 replicates of this sample, the coefficient of variation was 2.46%. Further, in a separate study, three separate samples were analyzed in replicates of ≥ 31 each to establish the standard deviation of the measurement. The results from this study are included in the table below.

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Date	Measurand	Donor	Replicates	Recovery	CV	Acceptable CV	Pass/Fail
20130820	WBC	251	32	98.9	2.98	< 7	Pass
20130820	WBC	244	34	97.6	3.68	< 7	Pass
20130827	WBC	381	18	98.4	2.98	< 7	Pass
20130820	NEU	251	32	100.6	0.9	< 12	Pass
20130820	NEU	244	34	102.6	0.8	< 12	Pass
20130827	NEU	381	18	99.6	0.8	< 12	Pass
20130820	LYM	251	32	98.6	1.2	< 6	Pass
20130820	LYM	244	34	101.2	1.2	< 6	Pass
20130827	LYM	381	18	101.5	1.5	< 6	Pass
20130820	MONO	251	32	99.6	2.5	< 12	Pass
20130820	MONO	244	34	82.2	1.9	< 12	Pass
20130827	MONO	381	18	95.6	3.1	< 12	Pass
20130820	EOS	251	32	101.9	4.3	< 17	Pass
20130820	EOS	244	34	101.4	3.1	< 17	Pass
20130827	EOS	381	18	105.9	4.4	< 17	Pass
20130820	BASO	251	32	91.8	8.4	< 18	Pass
20130820	BASO	244	34	98.7	8.8	< 18	Pass
20130827	BASO	381	18	91.9	6.1	< 18	Pass

11. Within day precision and between day precision: For enumeration assays such as this WBC assay, the dependence of imprecision on analyte concentration is determined by the number of particles enumerated in a fixed dilution and counting scheme. At lower concentrations, fewer particles are enumerated and the imprecision in the point estimate of particle concentration increases (governed by Poisson distribution). However, for WBC the normal range is narrow enough so that for all samples that fall in the normal range a significant number of particles is enumerated. Hence the concentration dependence of impression can be ignored. This argument is presented here to lay the basis for using sample recovery across different donors and different days as a way to characterize within and between day precision. In the table below, several plates run over several days have been combined and compared based on recovery. The variation in within-day precision can be clearly seen. The last column shows coefficient of variation calculated by aggregating all data points over different days.

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Date	*Mean recovery (%)*	*CV (%)*	*Number of data points*
2013-08-19	101.8	4.3	52
2013-08-20	99.7	3.8	112
2013-08-21	100.2	3.7	16
2013-08-22	100.6	6	48
2013-08-23	100.7	4.3	52
2013-08-24	100	7.4	8
2013-08-25	105.2	9.9	8
2013-08-26	99.4	6.2	24
2013-08-27	97	4.9	50
2013-08-29	97.9	6	8
2013-08-30	98.2	4.1	36
2013-09-01	103.4	10	12
2013-09-02	100.9	7.2	24
Across all days	**100.0**	**6.1**	**450**
Acceptable CV (%)		**< 7**	
Pass/Fail		**Pass**	

p. Establishing the Analytical Measurement Interval or Linearity

CLSI guidance document H26AE defines the analytical measurement interval or analytical measurement range as the range of analytical values that a method can directly measure on the specimen without any dilution, concentration, or other pretreatment not part of the usual assay process. The aim of this part of the validation program was to establish an analytical measurement range significantly wider than the typical clinically reportable interval. In effect, this implies that the said method will provide sensible results, without dilution, concentration or other pretreatment for any sample which the laboratory wishes to analyze. To this end, fresh whole blood samples were manipulated to yield a range of WBC concentrations from 0.2 to 70 x 10^9 cells/L. This range is significantly wider than any expected physiological range. These samples were processed in the usual way and analyzed for WBC concentration. Graphical representation and regression statistics for this dataset are included below. The goodness of fit establishes the "linearity" or the analytical measurement interval for this assay over 0.2 to 70 x 10^9 cells/L.

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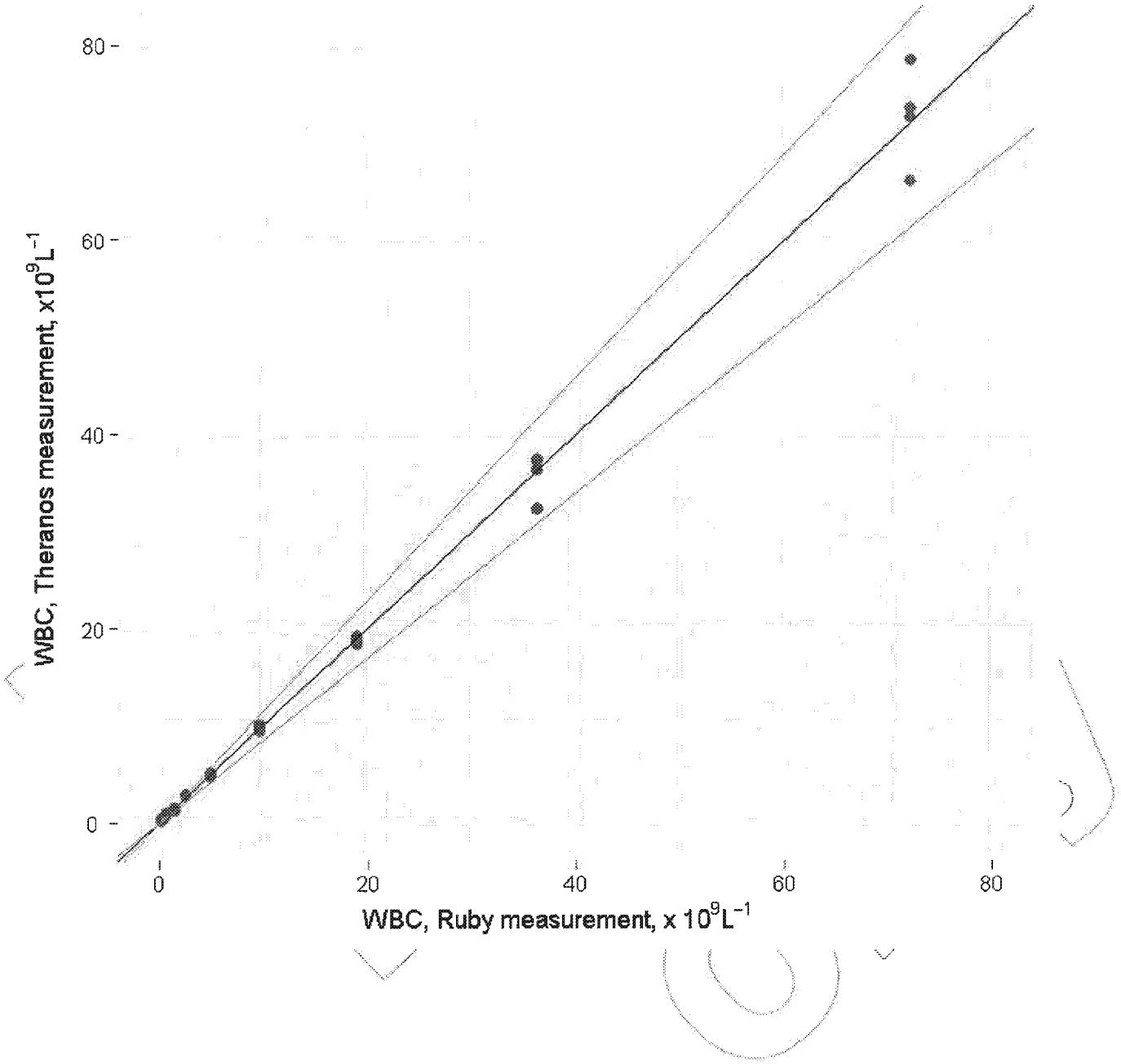
80
60
40
20
0
WBC, Theranos measurement, x10^{9}L^{-1}
0
20
40
60
80
WBC, Ruby measurement, x 10^{9}L^{-1}

Parameter	*Value*
Slope , [95% C.I.]	1.005, [0.984, 1.026]
Intercept , [95% C.I.]	0.024, [-0.485, 0.531]
R^2	0.99

q. Limit of blank (LoB) and carryover

Since the Theranos assay system uses a flow cytometer as the analytical device for enumeration of red blood cells, carryover from one sample to the next is a distinct possibility. In spite of including a wash step between two consecutive samples, a small finite amount of carryover is unavoidable. The impact of carryover is characterized as the change in the measured value of a 'low' sample when it is run subsequent to a 'high' sample. This study was performed together with characterization of the limit of blank because the effective limit of blank strongly depends upon carryover. For these studies, 8 blank samples were run consecutively and analyzed to get the limit of blank with no carryover considerations. Next, alternate high (WBC ~ 7.8 & 7.95 x 10^9/L) and blank samples were run to quantify the limit of blank with carryover.

Parameter	*Value*	*Unit*
Limit of blank, no carryover	0.00 ± 0.00	x 10^9/L
Limit of blank, with carryover	0.011 ± 0.006	x 10^9/L
Limit of blank, with carryover as percent of concentration of prior sample	0.14 ± 0.12	%

It is worth noting here that one of the reasons the limit of blank and carryover are significantly lower in the Theranos assay system as compared to predicate devices (where the norm is >1%, typically 1.5%) because of the specific epitope-based cell identification method used here. Due to epitope based identification, for a particle to be classified as a WBC, it must stain positive for the nuclear stain and CD45 and have side scatter in the correct range. Spurious events that satisfy these conditions are much fewer—hence the negligible limit of blank. Carryover is low due to extensive washes run after each sample run.

r. Limit of detection (LoD)

CLSI guidance document EP17-A2 defines the limit of detection (LoD) as the measurand quantitity value, obtained by a given measurement procedure, for which the probability of falsely claiming the absence of a measurand in a material is β, given a probability α of falsely claiming its presence. For the purpose of this validation program, α and β were selected to be 0.05. Guidelines from section 5.3.3 were used for designing the experiments and analyzing data.

Briefly, three low level samples were contrived from fresh whole blood at concentrations ranging from 50 to 200 x10^9/L. These samples were analyzed in quadruplicate along with blanks. From these data:

LoB = 0.000 (x10^9 /L)

J = number of low level samples run = 3 (consider only the lowest here)

L = number of results from these J samples = 12 (quadruplicate)

SD_L = standard deviation of all the L low level samples

$$LoD = LoB + SD_L\left(\frac{1.645}{1-\frac{1}{4(L-J)}}\right) = 0.005\ x\ 10^9\ cells/L$$

The limit of detection therefore is significantly lower than expected value for any physiological sample.

s. Limit of Quantification (LoQ)

CLSI guidance document EP17A2E defines the limit of quantification (LoQ) as the lowest amount of measurand in a material that can be quantitatively determined with stated accuracy under stated experimental conditions. Accuracy goals therefore need to be stated *a priori*. Then trial value of LoQ is picked based on the desired value the laboratory wants to claim. Based on the analytical measuring interval, a value of 0.055 x 10^9/L was selected as the target LoQ.

Accuracy goal was stated using the Westgard model:

$$TE = |bias| + 2\ SD$$

where, TE = the total error, bias is calculated as difference of measured value from the reference value of the sample at LoQ and SD is the standard deviation of measured values. The total error goal for this assay was defined to be 15% of the reference value of the LoQ sample.

The data and calculations tabulated below show that a sample at 0.055 x 10^9/L can be measured with a total error of less than 15%.

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WBC, measured (x10³/L)	*Reference value (x10³/L)*	*Absolute bias (x10³/L)*
0.055	0.055	0.001
0.055	0.055	0.000
0.056	0.055	0.002
0.051	0.055	0.003
0.056	0.055	0.002
0.053	0.055	0.002
0.050	0.055	0.004
0.058	0.055	0.003
0.055	0.055	0.001
0.055	0.055	0.000
0.056	0.055	0.002
0.051	0.055	0.003
SD = 0.0027		Mean = 0.002
TE = 0.002 + 2 x 0.0027 = 0.0075 = 13.8% of Ref value		

t. Interference (pathological samples)

CLSI guidance document H26A2E defines interference as an artifactual increase or decrease in apparent concentration or intensity of a measurand due to the presence of a substance that reacts nonspecifically with either the detecting reagent or the signal itself. In traditional hematology analyzers where WBCs are detected based on their size or light-scattering properties, presence of similar sized particles is the primary reason for interference. In the Theranos assay, WBCs are detected based on their light scattering properties but identified as WBCs based on their positive staining with a DNA stain and CD45. Consequently, interferants such as thrombocytosis and macrothrombocytes are not expected to have an impact on the assay.

One potential source of interference is nucleated RBCs, since the DNA in these cells would get labeled by the DNA stain. In the pathological samples tested herein, there were 4 samples that had NRBCs, but the effects of this interferant were not able to be determined.

Another major source of interference is the fact that a small subset of the population does not have the epitope used for detecting neutrophils (CD16). In this scenario, the neutrophils get

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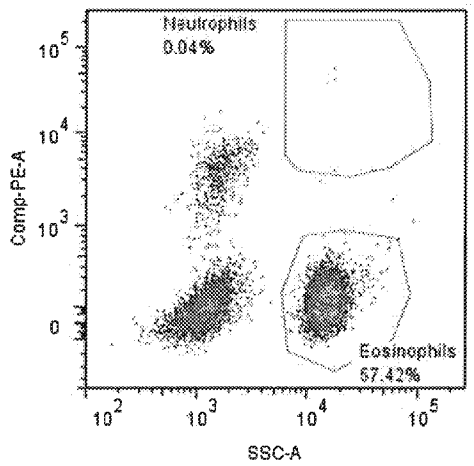
erroneously classified as eosinophils. In more than 1000 samples that have been analyzed by our laboratory over the last 2 years during which this assay was under development, fewer than 10 such samples have been encountered. An example of the fluorescence scattergram one such patient is show below.



Immature granulocytes have lower expression of CD16 than fully mature neutrophils (Hernandez-Campo et al., Cytometry Part B 72B:34-42 (2007)). In this assay they are occasionally indistinguishable from eosinophils, which also have high scatter and are negative for CD16. In this scenario there would be a flag for follow-up to determine the nature of the CD16-negative, high side scatter cells. An example scattergram is shown below.

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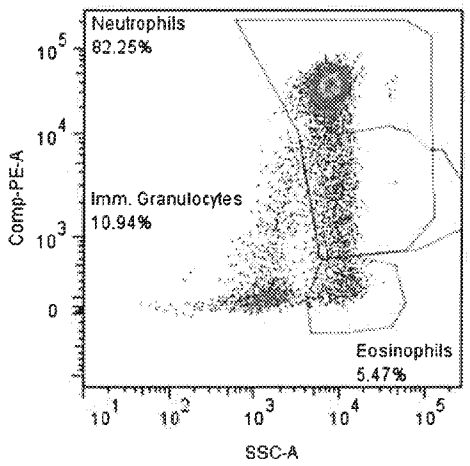
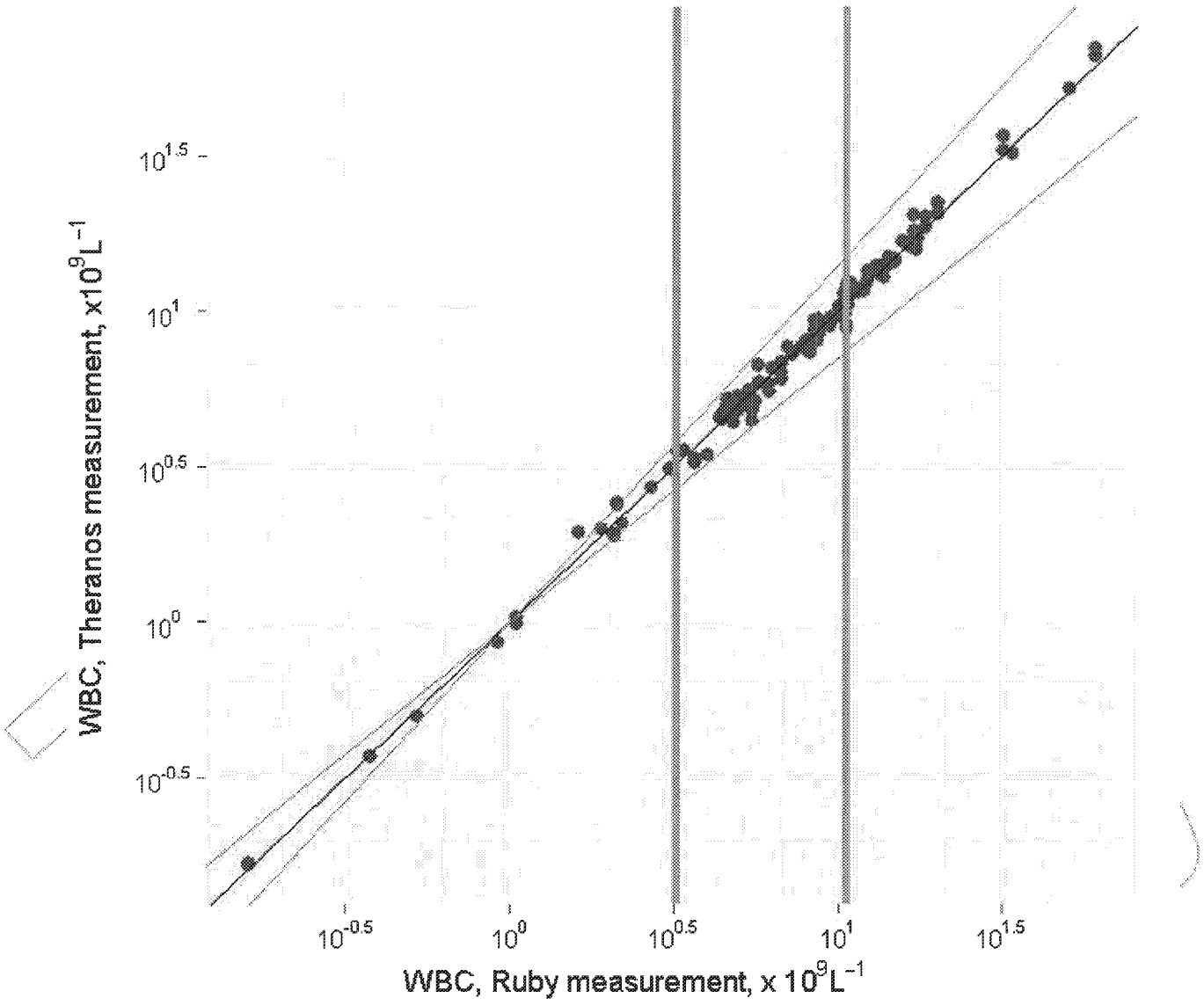


Pathological samples collected in the morning were sourced from UCSF laboratories and analyzed on the same day. The following conditions were reported in the UCSF laboratory reports.

Condition	*Number of samples*
Leukopenia (WBC < 3 x 10^9/L)	35
Leukocytosis (WBC > 11 x 10^9/L)	57
Granulocytopenia/Neutropenia (NEU/GRAN < 1.3 x 10^9/L)	29
Granulocytosis/Neutrophilia (NEU/GRAN > 7.0 x 10^9/L)	77
Lymphocytopenia (LYM < 0.8 x 10^9/L)	96
Lymphocytosis (LYM > 3.1 x 10^9/L)	16
Monocytosis (MONO > 0.7 x 10^9/L)	83
Monocytopenia (MONO < 0.2 x 10^9/L)	33
Eosinophilia (EOS > 0.4 x10^9/L)	26
Basophilia (BASO > 0.2%)	26

Internal Only



The figure demonstrates strong comparability of the Theranos measurement with predicate for these pathological samples.

The statistical measures of goodness of fit and bias are provided in the table below.

Parameter	*Value*
Number of data points	142
Slope , [95% C.I.]	1.08, [1.064,1.097]
Intercept , [95% C.I.]	-0.568, [-0.788, -0.348]
R^2	0.992
Mean bias (%)	0.35
t-test on mean bias, 95% CI	[-0.14, 0.85]
p-value	0.16

u. Precision at Medical Decision Limit

CLSI guidance document H26A2E, section 5.9.2 recommends that the precision of an assay at the medical decision limit be characterized during validation. For WBCs, the key medical decision limit is in the range of 0-2 x 10^9 /L, where decisions regarding treatment of severe neutropenia and leukopenia are made. To this end, WBC samples in the middle of this range (1 x 10^9 /L) were contrived and assayed for precision by running 24 consecutive replicates. For further evidence of the suitability of the assay for leukopenic samples, the reader is referred to section f, where data for more than 35 such samples is presented. Total error at MDL is 5.88%, which is within the TAE of 15%. Precision at MDL is acceptable.

Parameter	*Value*
Number of data points	24
Nominal value (x 10^9/L)	1
Mean of 24 replicates (x 10^9/L)	0.998
95% CI (x 10^9/L)	[0.985, 1.011]
p-value	$<2 \times 10^{-16}$
Mean bias (%)	-0.2
Precision (%CV)	2.84
Total Error at MDL (%)	0.2 + 2 x 2.84 = 5.88

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12. Method Comparison

c. Accuracy or Comparability with Predicate

In this section, data showing the comparability or accuracy of the Theranos assay with respect to the predicate assay is presented. The main objective of this exercise is to show that results obtained by Theranos method agree with a CLIA-compliant and FDA-approved hematology analyzer within the total error limits stipulated by CLIA. A secondary, but equally important, objective of this data is to also allow for transference of normal reference range from the predicate to the Theranos method. To increase the confidence in this comparison, pathological samples have also been included in this data set—this widens the range over which comparability is demonstrated.

The figure below shows data for 244 unique samples with 628 total data points. Statistical measures of goodness-of-fit and bias are provided below.

Parameter	*Value*
Number of data points, unique samples	628, 244
Slope , [95% C.I.]	1.073, [1.063, 1.083]
Intercept , [95% C.I.]	-0.507, [-0.596, -0.418]
R^2	0.986
Mean bias (%)	0.35
t-test on mean bias, 95% CI	[-0.14, 0.85]
p-value	0.16
Total allowable error, % (from CLIA 1988)	±15
Precision, (%CV)	3.2
Total error, %	0.35 + 2 x 3.2 = 6.75

The total error in measurement with respect to Cell-Dyn Ruby is 6.75%, well within the 15% total allowable error.

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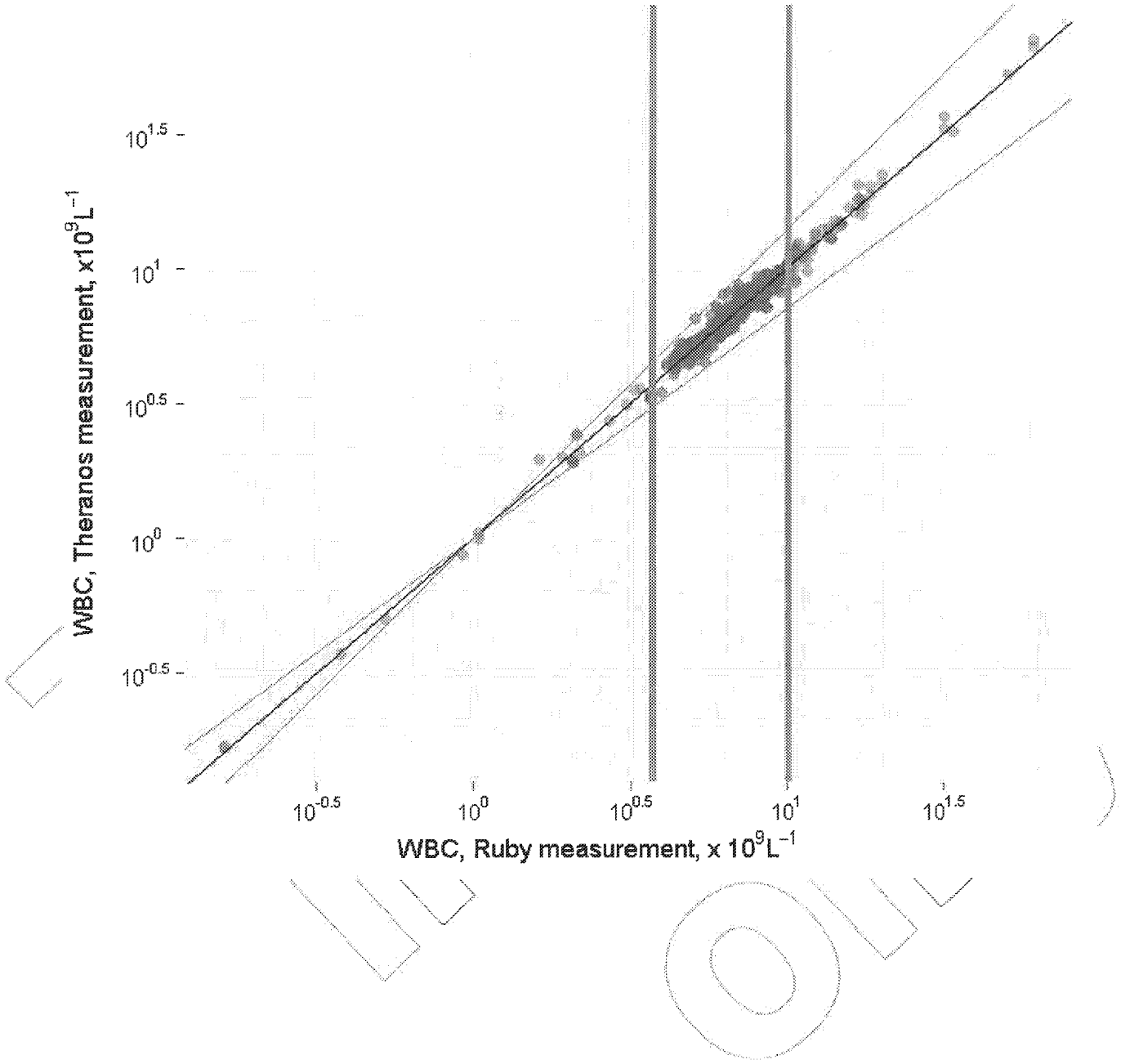
WBC, Theranos measurement, x10^{9}L^{-1}
$10^{1.5}$
10^{1}
$10^{0.5}$
10^{0}
$10^{-0.5}$
$10^{-0.5}$
10^{0}
$10^{0.5}$
10^{1}
$10^{1.5}$
WBC, Ruby measurement, x 10^9L^{-1}

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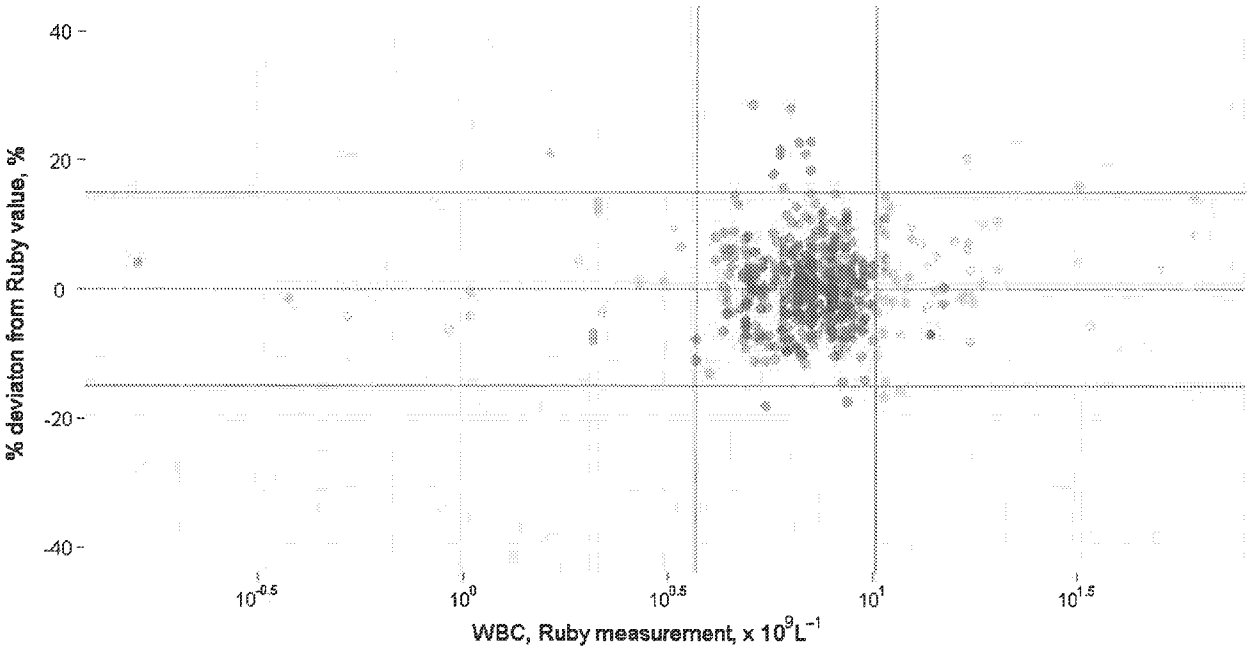

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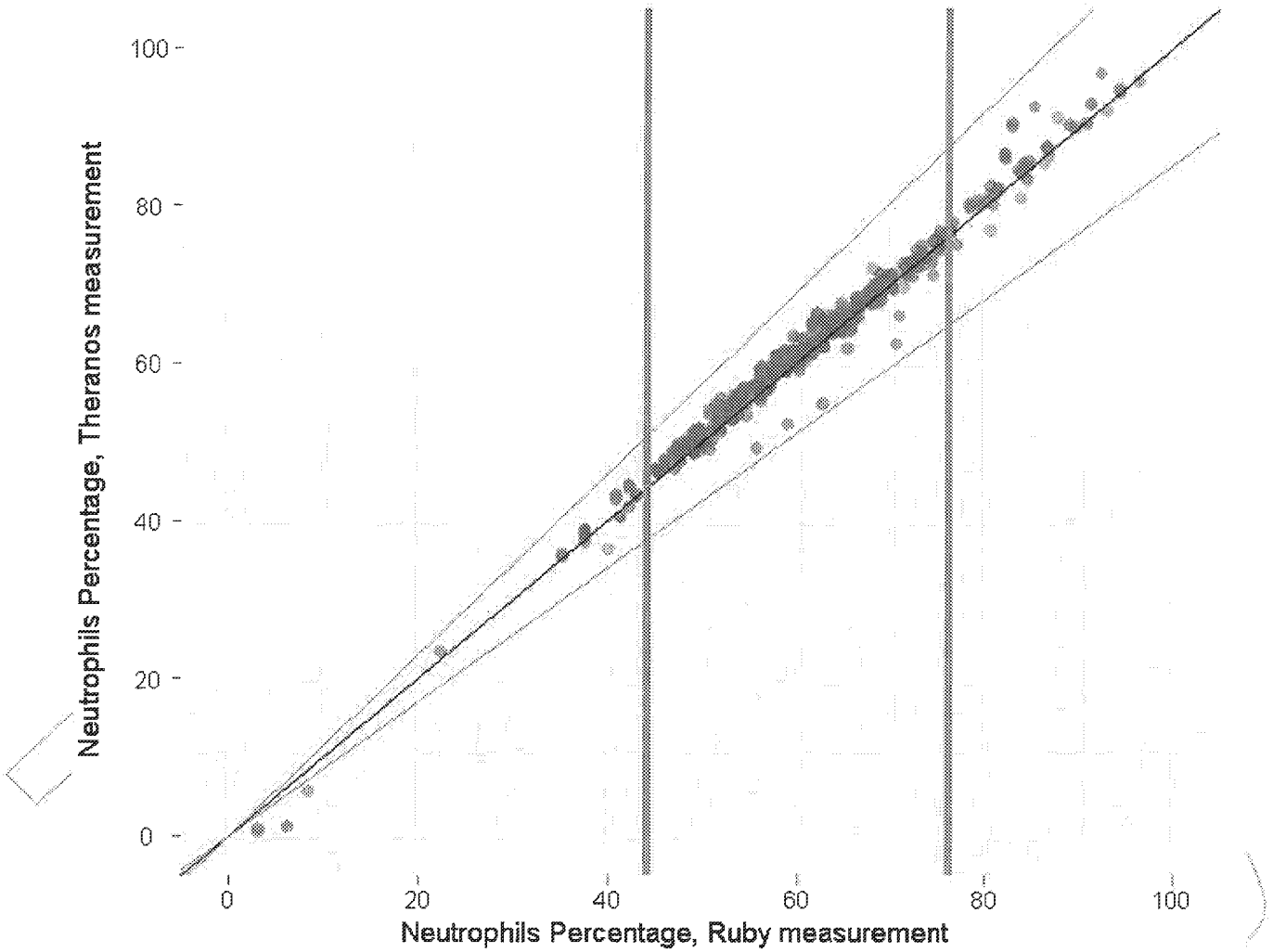
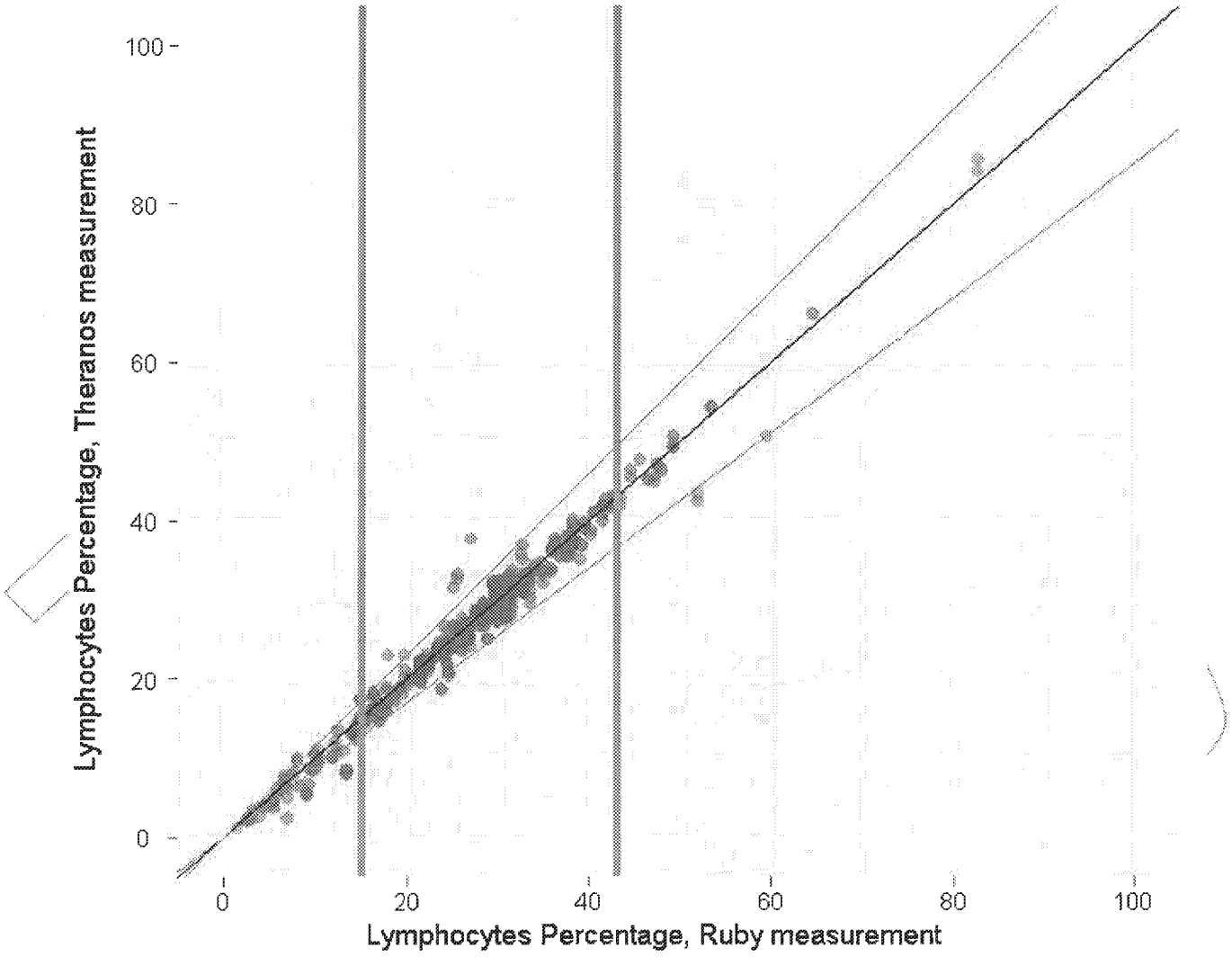


Parameter	*Value*
Number of data points, unique samples	628, 244
Slope , [95% C.I.]	1.011, [1.001, 1.020]
Intercept , [95% C.I.]	0.147, [-0.421,0.716]
R^2	0.987
Mean bias (%)	0.84
t-test on mean bias, 95% CI	[0.29, 1.39]
p-value	0

Total allowable error, % (from CLIA 1988, from Westguard)	NA, ± 16.52
Precision, (%CV)	1
Total error, %	0.84 + 2 x 1 = 2.84



Parameter	Value

Number of data points, unique samples	628, 244
Slope , [95% C.I.]	1.005, [0.993,1.017]
Intercept , [95% C.I.]	-0.511, [-0.871,-0.151]
R^2	0.977
Mean bias (%)	-2.19
t-test on mean bias, 95% CI	[-2.85,-1.525]
p-value	0
Total allowable error, % (from CLIA 1988, from Westguard)	NA, ± 8.36
Precision, (%CV)	1.3
Total error, %	2.19 + 2 x 1.3 = 4.8

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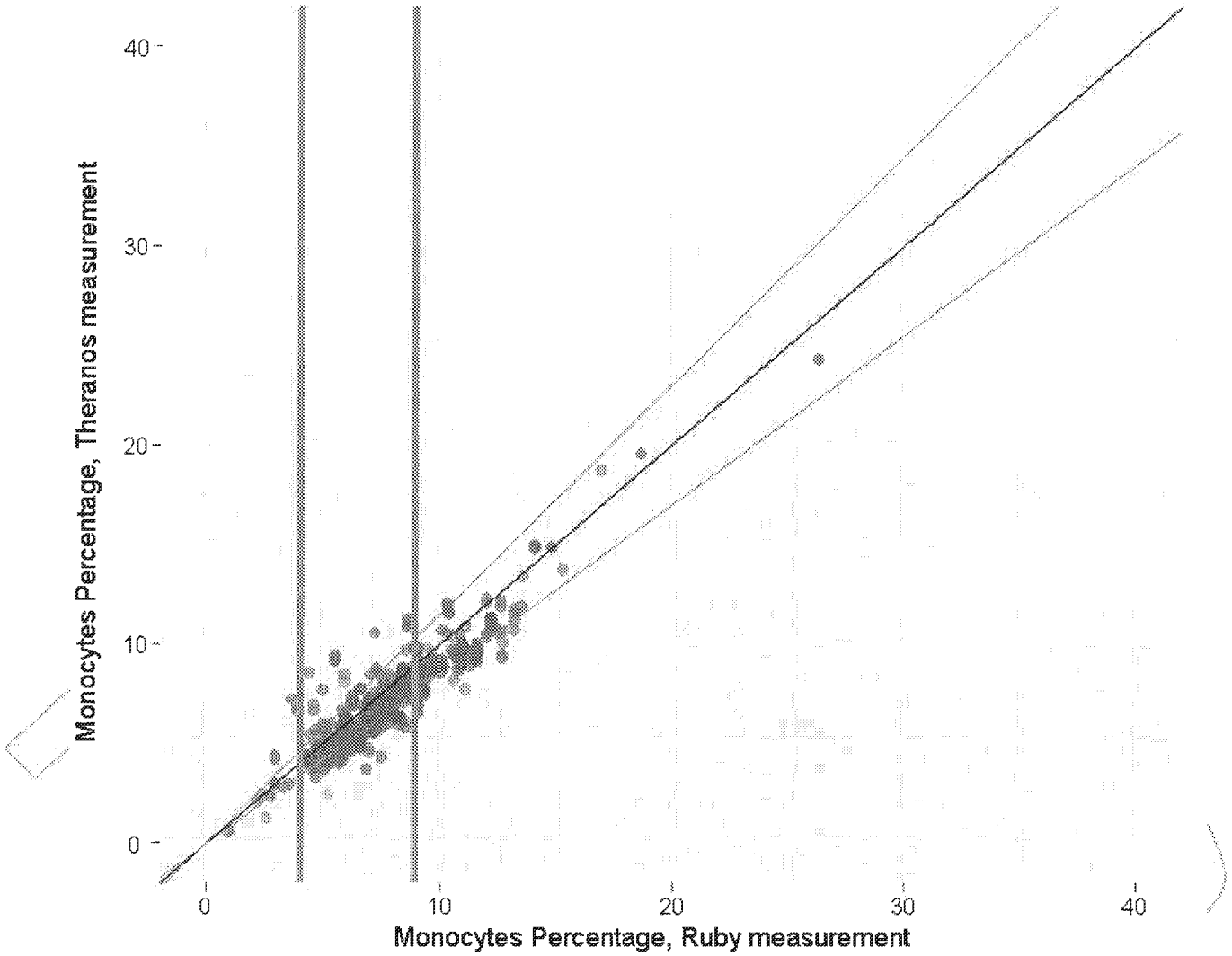
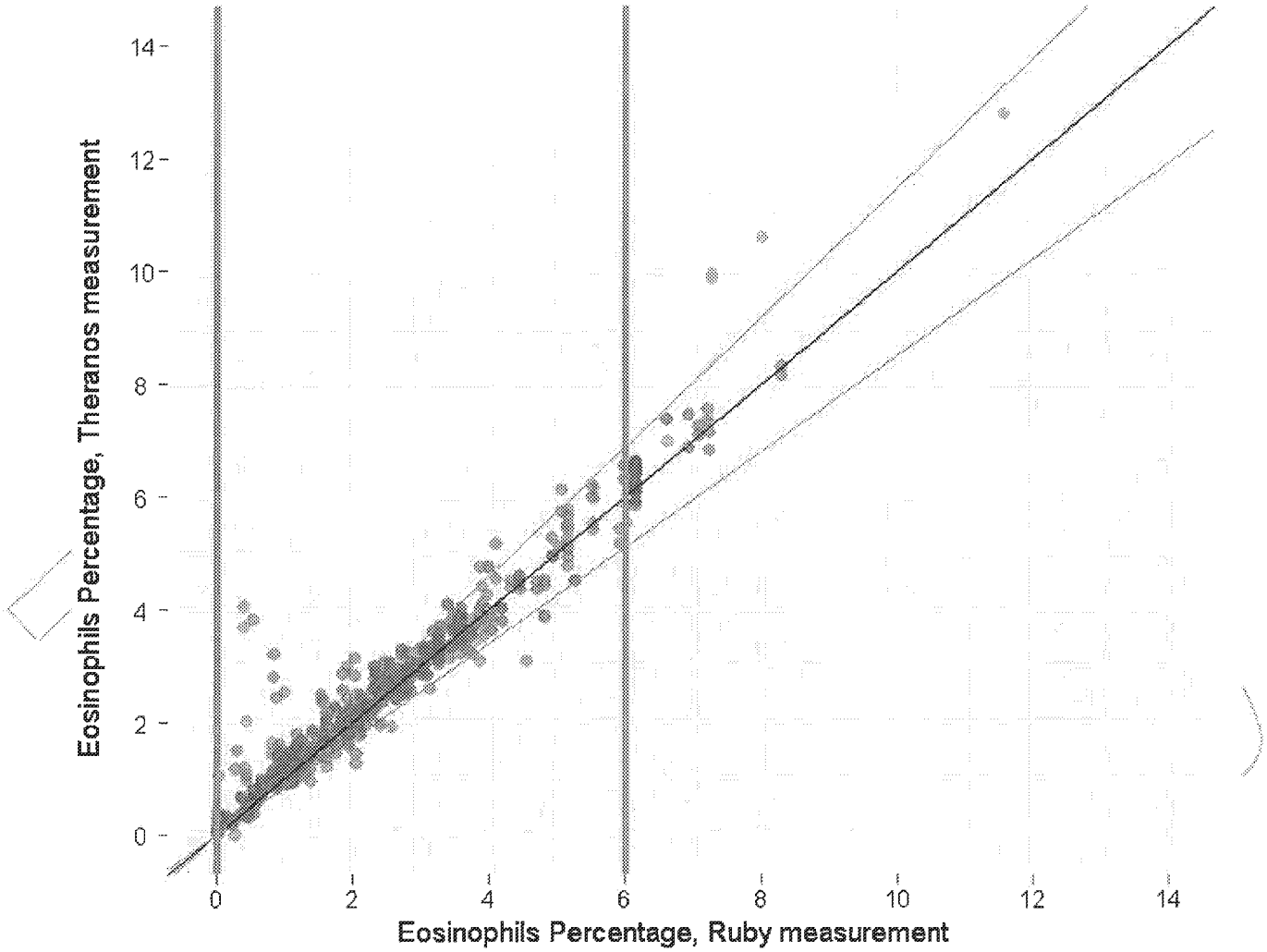


Parameter	*Value*
Number of data points, unique samples	628, 244
Slope , [95% C.I.]	0.867, [0.838,0.897]
Intercept , [95% C.I.]	0.439, [0.197,0.681]
R^2	0.842
Mean bias (%)	-6.75
t-test on mean bias, 95% CI	[-7.99,-5.5]
p-value	0

Total allowable error, % (from CLIA 1988, from Westguard)	NA, ± 23.2
Precision, (%CV)	2.5
Total error, %	6.75 + 2 x 2.5 = 11.75



Parameter	*Value*
Number of data points, unique samples	628, 244
Slope , [95% C.I.]	1.013, [0.993,1.033]
Intercept , [95% C.I.]	0.134, [0.068,0.2]

R^2	0.942
Mean bias (%)	4.63
t-test on mean bias, 95% CI	[NA]
p-value	0
Total allowable error, % (from CLIA 1988, from Westguard)	NA, ± 33.71
Precision, (%CV)	3.9
Total error, %	4.63 + 2 x 3.9 = 12.43

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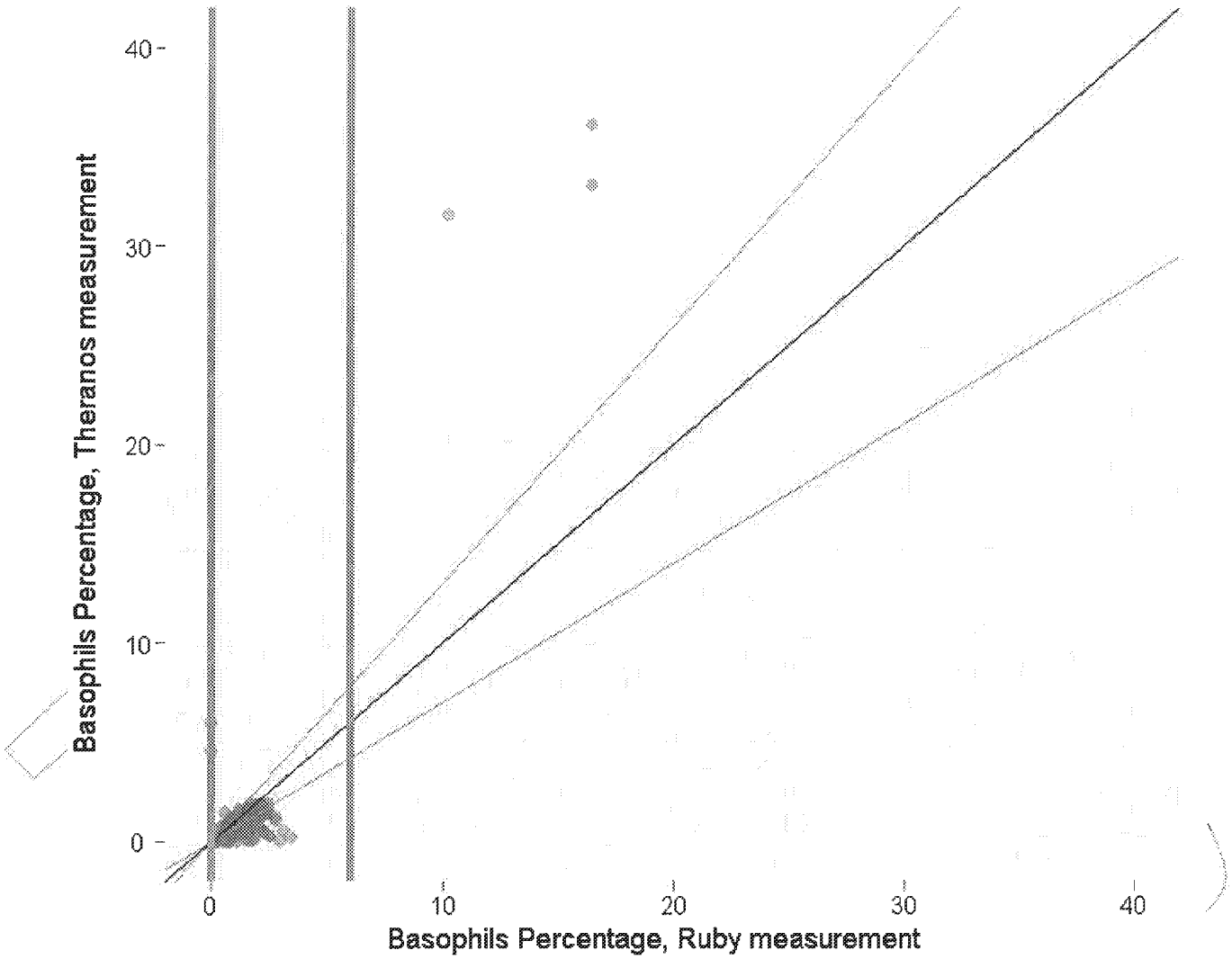

Table for basophils is not presented here, pending more data over a wider range.

b. Transferance and Verification of Reference Intervals

In CLSI guidance document C28A3, section 10 the determination of reference method by transference is discussed. This strategy allows transfer of reference range from the predicate method to the test method, provided the following criteria are satisfied.

5. The comparability of the analytical system
6. The comparability of the test subject population

Comparability of the test population follows from the fact that these tests are being validated for the same clinical laboratory. Comparability of the analytical system has been established in the foregoing section.

Measurand	*Units*	*slope*	*intercept*	*Reference range, low*	*Reference range, high*	*Transferred, Low*	*Transferred, high*
WBC	x 10^9/L	1.073	-0.507	3.7	10.1	3.5	10.3
NEU	%	1.011	0.147	39.3	73.7	39.9	74.7
LYM	%	1.005	-0.511	18	48.3	17.6	48.0
MONO	%	0.867	0.439	4.4	12.7	4.3	11.4
EOS	%	1.013	0.134	0.6	7.3	0.7	7.5
BASO	%	1.995	-1.414	0	1.7	0.0	2.0

18. Verification of Pre-analytical methods

a. Verification of Reference Intervals for fingerstick samples

Theranos assays and systems have the ability to process both fingerstick and venous samples. Samples are collected with the Theranos blood collection device which comprises of a capillary channel and an evacuated nanotainer. In order to capture the effect of this collection modality on the performance of the WBC assay, more than 50 nanotainer-samples were analyzed, using the same system as mentioned in earlier sections of this report. The correlation between WBC concentration as measured on Theranos system with fingerstick samples and as measured on the Abbott Cell-Dyn Ruby using a paired venous sample is shown below.

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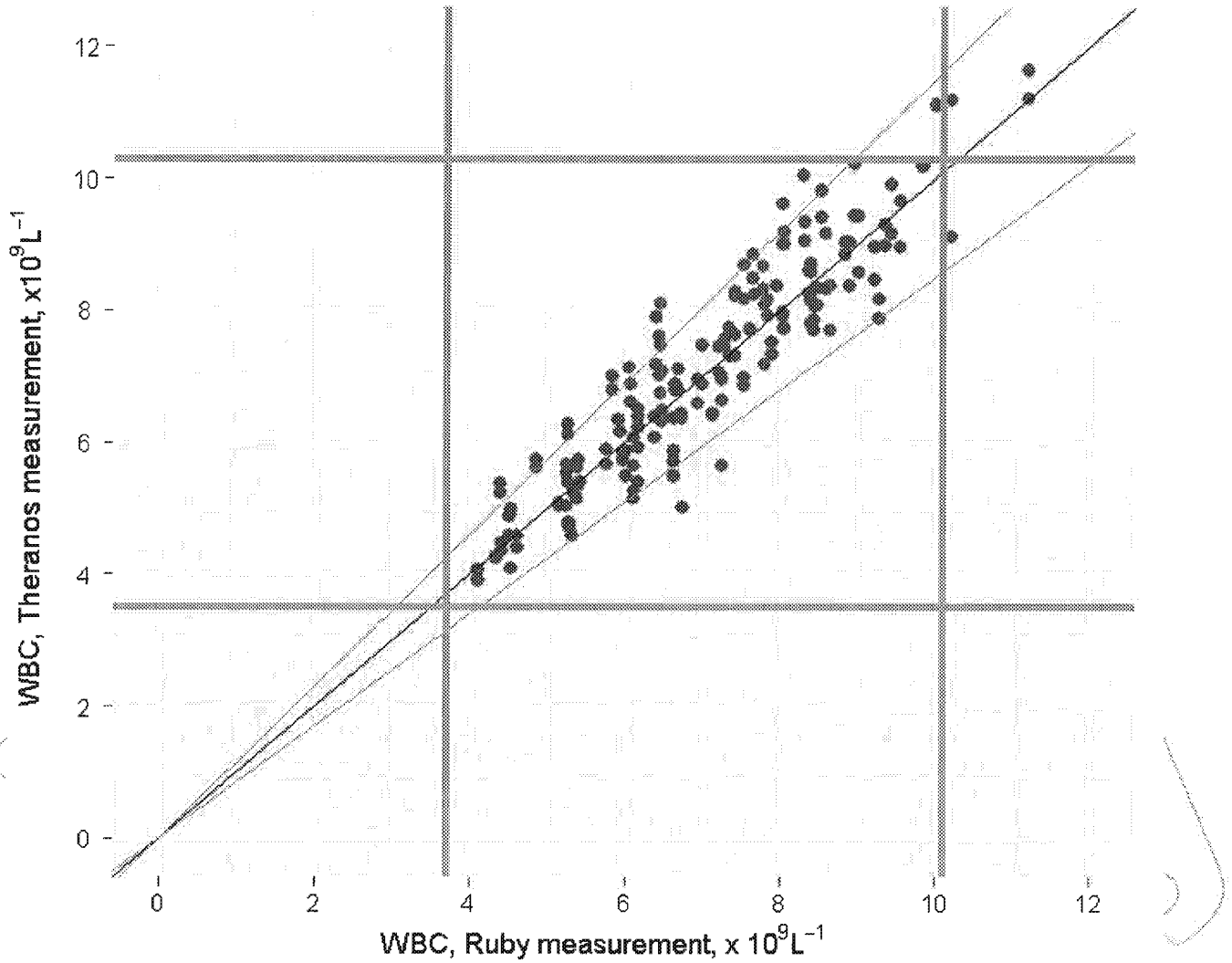
WBC, Theranos measurement, x10^{9}L^{-1}
WBC, Ruby measurement, x 10^{9}L^{-1}
0
2
4
6
8
10
12

Parameter	*Value*
Number of data points, unique samples	181, 93
Slope , [95% C.I.]	0.997, [0.937, 1.037]
Intercept , [95% C.I.]	0.141, [-0.293, 0.575]
R^2	0.857
Mean bias (%)	1.8
t-test on mean bias, 95% CI	[0.46,3.13]
p-value	0.01
Total allowable error, % (from CLIA 1988)	±15
Precision, (%CV)	3.2
Total error, %	1.8 + 2 x 3.2 = 8.2

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Theranos Hemoglobin Assay

19. Overview
20. Principle
21. Method Characterization
    a. Precision
    b. Establishing the Analytical Measurement Interval or Linearity
    c. Limit of Blank and Carryover
    d. Limit of Detection
    e. Limit of Quantification
    f. Interference (Pathological samples)
    g. Precision at Medical Decision Limit
22. Method Comparison
    a. Accuracy or Comparability with Predicate
    b. Transferance and Verification of Reference Intervals
23. Verification of Pre-analytical methods
    a. Verification of Reference Intervals for fingerstick samples

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10. Overview

An absorbance based hemoglobin assay is validated against Abbott Cell-Dyn Ruby, an automated hematology analyzer.

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Principle

In this assay, Drabkins reagent (a mix of alkaline ferricyanide and cyanide) is used to convert all hemoglobin in lysed whole blood into cyanmethemoglobin—a derivative of hemoglobin that absorbs with a peak at 540nm. All forms of hemoglobin are converted to this one form (except sulf-form, which exists only in minute quantities). The absorbance can therefore be quantitatively related to hemoglobin concentration.

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11. Method Characterization

v. Precision:

CLSI standard EP05-A2 defines precision as the closeness of agreement between independent test/measurement results obtained under stipulated conditions. The term stipulated conditions encompasses a wide variety of contexts encountered in the process of clinical analysis. For the purpose of this validation study, precision was measured and characterized in the following contexts:

- within plate (or run) precision
- across plate (or run) precision
- within day precision
- between day precision

The main objective behind characterization of precision under the above conditions is to demonstrate that this method is robust to the different sources of variation inherent in the analytical method.

13. Within plate (or run) precision: Sixteen replicates of the same sample were analyzed on an assay plate. The coefficient of variation across these replicates characterizes the within run precision for this method.

Hemoglobin	*plate 1*	*plate 2*	*plate 3*
Mean of 20 replicates (g/dL)	14.3	13.2	16.2
CV (%)	2.9	2.8	3.3
Acceptable CV (%)	< 3.5	< 3.5	< 3.5
Pass/Fail	Pass	Pass	Pass

Across plate (or run) precision: The foregoing data also allows us to characterize the across run precision, as the three plates had the same sample across them. Across all 20 x 3 = 60 replicates of this sample, the coefficient of variation was 3.1%.

14. Within day precision and between day precision: Blood samples were analyzed over multiple days and compared with predicate to calculate recovery. The precision of this recovery is reported as a surrogate for long-term precision in this case.

Date	*Mean recovery (%)*	*CV (%)*	*Number of data points*
2013-09-04	100.0	1.8	44
2013-09-05	100.5	2.7	80
2013-09-06	100.0	2.35	48
Across all days	**100.3**	**2.4**	**172**
Acceptable CV (%)		**< 3.5**	
Pass/Fail		**Pass**	

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w. Limit of blank (LoB) and carryover

Since this assay measured hemoglobin in blood, very low values of the measurand are non-physiological—incompatible with life. Further, the method used for preparation of the sample precludes carryover. Hence, both limit of blank and carryover are not considered here.

x. Limit of detection (LoD)

Please see above.

y. Limit of Quantification (LoQ)

Please see above.

z. Precision at Medical Decision Limit

CLSI guidance document H26A2E, section 5.9.2 recommends that the precision of an assay at the medical decision limit be characterized during validation. For hemoglobin, the key medical decision limit is in the range of 6-10 x 10^9 /L, where transfusion decisions are made. To this end, Hgb samples in the middle of this range (8 g/dL) were contrived and assayed for precision by running 96 consecutive replicates. For further evidence of the suitability of the assay for thrombocytopenic samples, the reader is referred to section f where data for more than 40 such samples is presented. Total error at MDL of 4.6% is within the TAE of 7%. Precision at MDL is acceptable.

Parameter	*Value*
Number of data points	96
Nominal value (x 10^9/L)	8.1
Mean of 96 replicates (x 10^9/L)	8.2
95% CI (x 10^9/L)	[8.15, 8.24]
p-value	$<2 \times 10^{-16}$
Mean bias (%)	1.2
Precision (%CV)	1.7
Total Error at MDL (%)	1.2 + 2 x 1.7 = 4.6

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15. Method Comparison

d. Accuracy or Comparability with Predicate

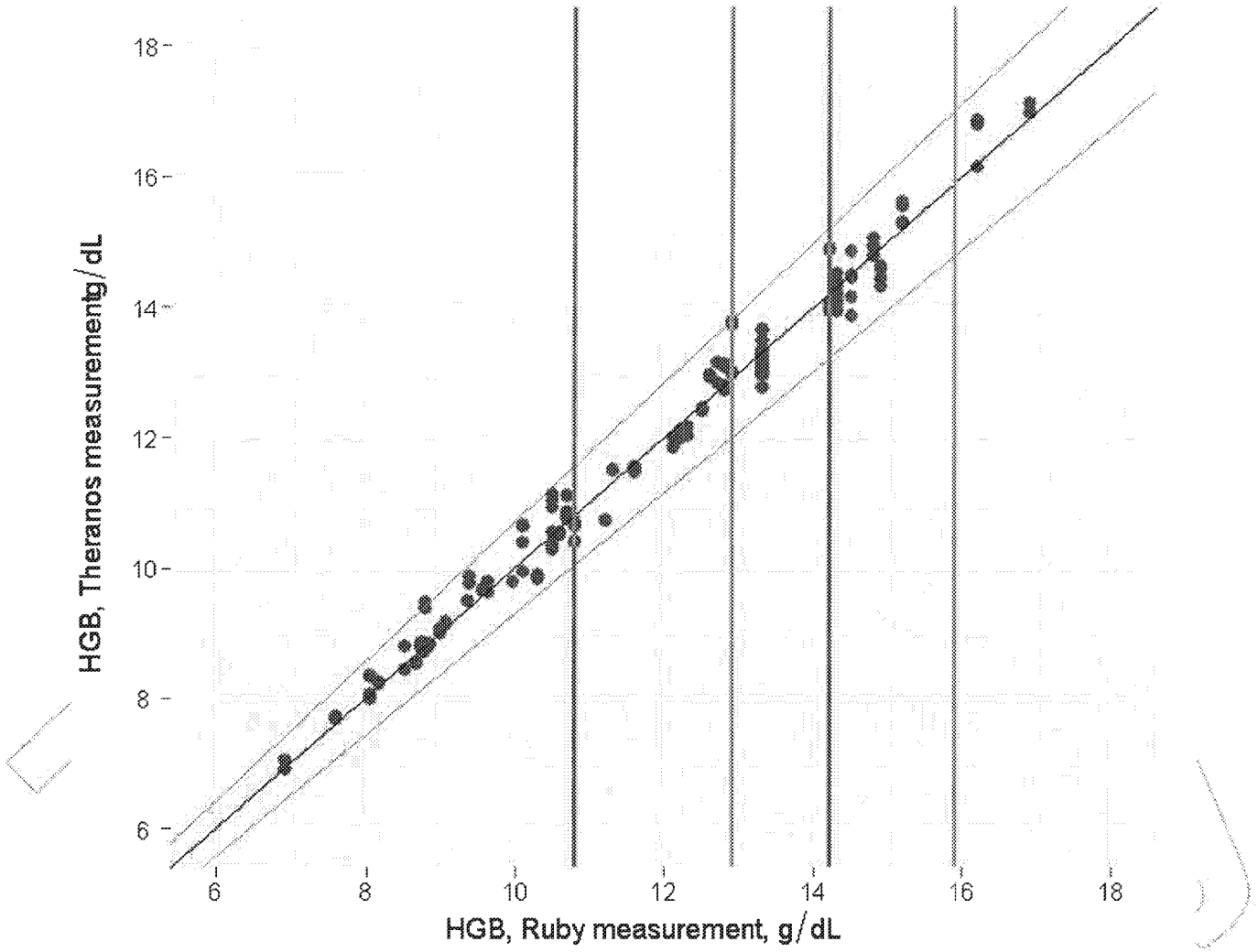
In this section, data showing the comparability or accuracy of the Theranos assay with respect to the predicate assay is presented. The main objective of this exercise is to show that results obtained by Theranos method agree with a CLIA-compliant and FDA-approved hematology analyzer within the total error limits stipulated by CLIA. A secondary, but equally important, objective of this data is to also allow for transference of normal reference range from the predicate to the Theranos method. To increase the confidence in this comparison, pathological samples have also been included in this data set—this widens the range over which comparability is demonstrated.

The figure below shows data for 62 unique samples with 172 total data points. Statistical measures of goodness-of-fit and bias are provided below.

Parameter	*Value*
Number of data points, unique samples	172, 62
Slope , [95% C.I.]	0.985, [0.959,1.011]
Intercept , [95% C.I.]	0.205, [-0.1122,0.522]
R^2	0.987
Mean bias (%)	0.31
t-test on mean bias, 95% CI	[-0.08, 0.69]
p-value	0.12
Total allowable error, % (from CLIA 1988)	±7
Precision, (%CV)	2.1
Total error, %	0.31 + 2 x 2.1 = 4.51
% points with more than 7% total error	0

The total error in measurement with respect to Cell-Dyn Ruby is 4.5%, significantly less than the CLIA mandated 7%.

Theranos Internal Only



b. Transferance and Verification of Reference Intervals

In CLSI guidance document C28A3, section 10 the determination of reference method by transference is discussed. This strategy allows transfer of reference range from the predicate method to the test method, provided the following criteria are satisfied.

7. The comparability of the analytical system

8. The comparability of the test subject population

Comparability of the test population follows from the fact that these tests are being validated for the same clinical laboratory. Comparability of the analytical system has been established in the foregoing section. The correlation between Theranos method and Abbott Cell-Dyn Ruby is described by:

$$y = 0.985x - 0.205, \qquad r^2 = 0.987$$

The confidence intervals on the slope and the intercept do span 1 and 0 respectively, thus showing the small bias of the assay. The reference range for Theranos assay:

Females: [10.8, 14.2] transfers to [10.8, 14.2]
Males: [12.8, 15.9] transfers to [12.8, 15.9]

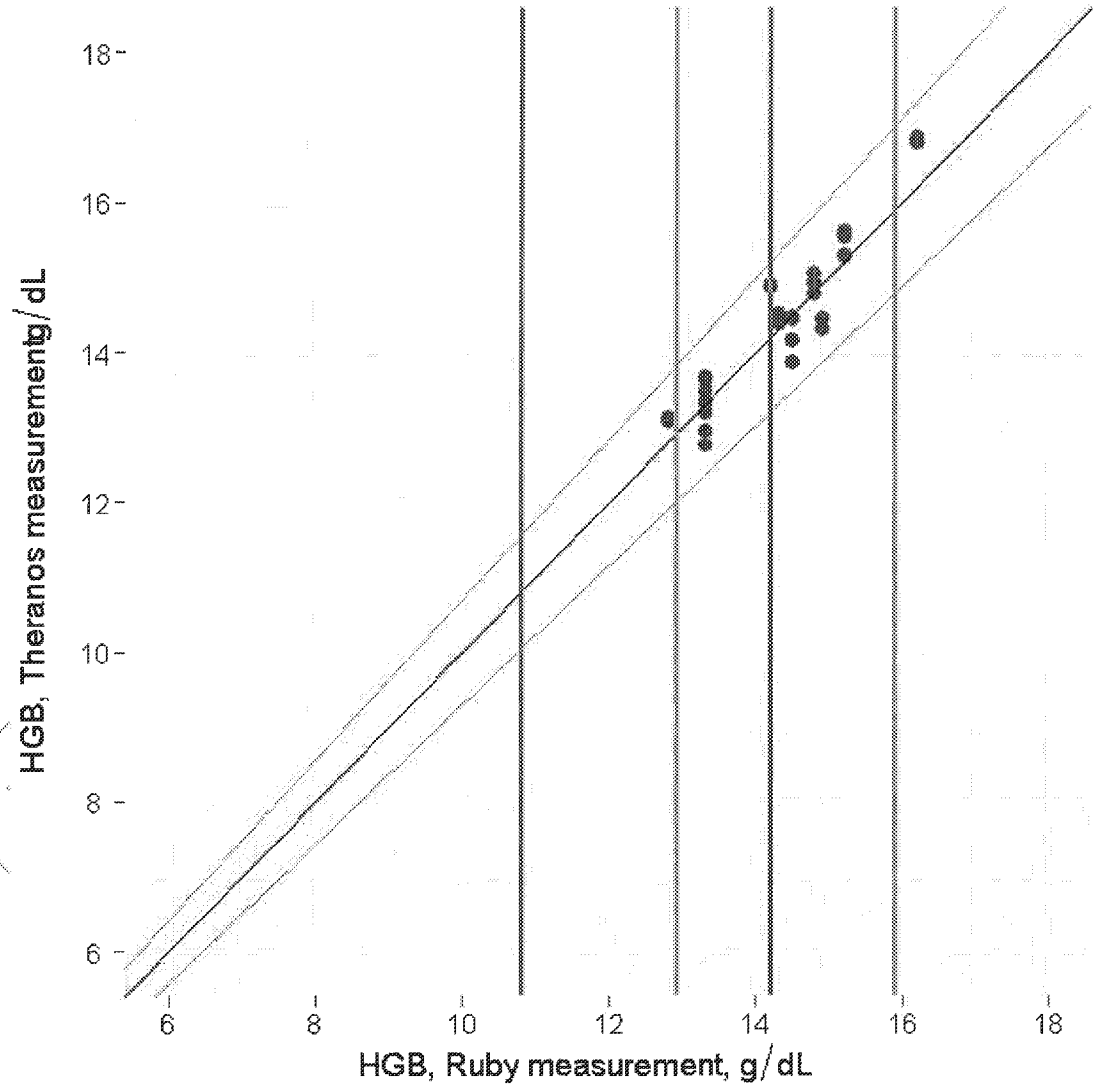
This calculation shows that the reference range can be directly transferred. The new reference range of the Theranos HGB assay is therefore unchanged.

24. Verification of Pre-analytical methods

a. Verification of Reference Intervals for fingerstick samples

Theranos assays and systems have the ability to process both fingerstick and venous samples. Samples are collected with the Theranos blood collection device which comprises of a capillary channel and an evacuated nanotainer. In order to capture the effect of this collection modality on the performance of the platelet assay, more than 50 nanotainer-samples were analyzed, using the same system as mentioned in earlier sections of this report. The correlation between platelet concentration as measured on Theranos system with fingerstick samples and as measured on the Abbott Cell-Dyn Ruby using a paired venous sample is shown below.

Theranos Internal Only



Parameter	Value
Number of data points, unique samples	30, 15
Slope , [95% C.I.]	0.989, [0.8, 0.95]
Intercept , [95% C.I.]	0.213, [0.012, 0.413]
R^2	0.89

Revision Level	Effective Date	Initiator	DCO Number
A	9/9/2013	C. Pangarkar	
B	11/14/2015	C. Pangarkar	DCO00108

Section Number	Description and Justification of Changes
All	Initial Release
B	Update to current practices

Theranos Internal Only

EXHIBIT 16

Brecher, Aaron

From: Volkar, Kelly (USACAN) <Kelly.Volkar@usdoj.gov>
Sent: Friday, November 5, 2021 8:00 PM
To: Coopersmith, Jeffrey; Walsh, Amy; Cazares, Stephen; Brecher, Aaron
Cc: Leach, Robert (USACAN); Bostic, John (USACAN); Schenk, Jeffrey (USACAN); Wachs, Madeline (USACAN)
Subject: U.S. v. Balwani - Witness & Exhibit List & Amended Bill of Particulars
Attachments: 2021.11.05 Gov Witness List - Balwani.pdf; 2021.11.05 Gov Exhibit List - Balwani.pdf; 2021.11.05 Govt Amended Bill of Particulars Balwani.pdf

Counsel,

Please find attached the government's witness list and exhibit list. For exhibits, the Court requested Defendant Holmes's counsel to continue numbering exhibits after ours and to use "TX" or "Trial Exhibit" as a prefix (rather than "DX" or "PX"), and we expect the Court may ask the same of your team. Please begin the numbering of your exhibits at 7000 per the Court's request.

Finally, please find attached an amended Bill of Particulars, which we intend to file with the Court in the coming weeks.

Best,
Kelly

Kelly I. Volkar
Assistant United States Attorney
Northern District of California
450 Golden Gate Avenue, 11th Floor
San Francisco, CA 94102
[redacted]
Kelly.Volkar@usdoj.gov

EXHIBIT 17

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
Western Division of Survey and Certification
San Francisco Regional Office
90 7th Street, Suite 5-300 (5W)
San Francisco, CA 94103-6707

CENTERS FOR MEDICARE & MEDICAID SERVICES

Refer to: WDSC- GKY

IMPORTANT NOTICE – PLEASE READ CAREFULLY

January 25, 2016

Sunil Dhawan, M.D., Director
Theranos, Inc.
7333 Gateway Boulevard
Newark, CA 94560

CLIA Number: 05D2025714

RE: CONDITION LEVEL DEFICIENCIES – IMMEDIATE JEOPARDY

Dear Dr. Dhawan:

In order for a laboratory to perform testing under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), Public Law 100-578, it must comply with all CLIA requirements. These requirements are found in section 353 of the Public Health Service Act (42 U.S.C. 263a) and 42 Code of Federal Regulations, Part 493 (42 CFR 493). Federal regulations require onsite surveys to determine whether or not a laboratory is in compliance with the applicable regulations. Compliance with these regulations is a condition of certification for the CLIA program.

The Centers for Medicare & Medicaid Services (CMS) conducted a CLIA recertification and complaint survey of the laboratory. The onsite survey was completed on November 20, 2015. However, the survey concluded with the receipt of critical information received from the laboratory on December 23, 2015. As a result of the survey, it was determined that your facility is not in compliance with all of the Conditions required for certification in the CLIA program. In addition, based on the Condition-level requirement at 42 C.F.R. § 493.1215, Hematology, it was determined that the deficient practices of the laboratory pose immediate jeopardy to patient health and safety. (Immediate jeopardy is defined by the CLIA regulations as a situation in which immediate corrective action is necessary because the laboratory's non-compliance with one or more Condition-level requirements has already caused, is causing, or is likely to cause, at any time, serious injury or harm, or death, to individuals served by the laboratory or to the health and safety of the general public.) Specifically, the following Conditions were not met:

D5024: 42 C.F.R. § 493.1215	Condition: Hematology;
D5400: 42 C.F.R. § 493.1250	Condition: Analytic systems;
D6076: 42 C.F.R. § 493.1441	Condition: Laboratories performing high complexity testing; laboratory director;
D6108: 42 C.F.R. § 493.1447	Condition: Laboratories performing high complexity testing; technical supervisor; and,

FOIA Confidential Treatment Requested by Theranos

D6168: 42 C.F.R. § 493.1487 Condition: Laboratories performing high complexity testing; testing personnel.

In addition, other standards were also found to be not met. Enclosed is Form CMS-2567, Statement of Deficiencies, listing all the deficiencies found during the survey.

When a laboratory's deficiencies pose immediate jeopardy, CMS requires the laboratory to take immediate action to remove the jeopardy and come into Condition-level compliance. Laboratories that do not meet the Condition-level requirements of CLIA may not be certified to perform laboratory testing under the CLIA program.

The laboratory has 10 CALENDAR DAYS from the date of receipt of this notice to provide CMS' Central Office and San Francisco Regional Office with a credible allegation of compliance and acceptable evidence of correction documenting that the immediate jeopardy has been removed and that action has been taken to correct all of the Condition-level deficiencies in question.

Please document the laboratory's allegation of compliance using the enclosed Form CMS-2567, Statement of Deficiencies, in the columns labeled "Provider Plan of Correction" and "Completion Date" located on the right side of the form, keying your responses to the deficiencies on the left. The laboratory director must sign, date and return the completed Form CMS-2567 documented with a credible allegation of compliance WITHIN 10 CALENDAR DAYS from the date of receipt of this notice. You must also submit documented evidence that verifies that the corrections were made. (Your allegation of compliance will be included in the public record of the inspection.)

For your information, a credible allegation of compliance is a statement or documentation that is:

1) Made by a representative of a laboratory with a history of having maintained a commitment to compliance and taking corrective action when required;

2) Realistic in terms of the possibility of the corrective action being accomplished between the date of the survey and the date of the allegation; and

3) Indicates resolution of the problems.

In addition, acceptable evidence of correction must include:

1) Documentation showing what corrective action(s) have been taken for patients found to have been affected by the deficient practice;

2) How the laboratory has identified other patients having the potential to be affected by the same deficient practice and what corrective action(s) has been taken;

3) What measure has been put into place or what systemic changes have been made to ensure that the deficient practice does not recur; and

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Trial Exh. 4621 Page 0002

4) How the corrective action(s) are being monitored to ensure the deficient practice does not recur.

If the laboratory submits a credible allegation of compliance and acceptable evidence of correction that the laboratory has removed jeopardy and come into Condition-level compliance, and we are able to verify compliance with all CLIA requirements through a follow-up survey, sanctions will not be imposed. If the laboratory does not submit a credible allegation of compliance and acceptable evidence of correction, we will not conduct a follow-up survey.

If jeopardy is not removed and the laboratory does not come into Condition-level compliance, CMS will take sanction action(s) against the laboratory's CLIA certificate. If necessary, we will advise the laboratory in writing of the sanction(s) to be imposed and/or enforcement action(s) that will be taken. These sanctions may include alternative sanctions (Civil Money Penalty of up to $10,000 per day of non-compliance pursuant to 42 C.F.R. §493.1834, Directed Plan of Correction pursuant to 42 C.F.R. § 493.1832, and/or State Onsite Monitoring pursuant to 42 C.F.R. § 493.1836) and principal sanctions (suspension, limitation and/or revocation of the laboratory's CLIA certificate and cancellation of the laboratory's approval for Medicare payments pursuant to 42 C.F.R. § 493.1814).

Please note that the routine survey takes an overview of the laboratory through random sampling. By its nature, the routine survey may not find every violation that the laboratory may have committed. It remains the responsibility of the laboratory and its director to ensure that the laboratory is at all times following all CLIA requirements, to identify any problems in the laboratory and take corrective action specific to the problems, and to institute appropriate quality assurance measures to ensure that the deficient practices do not recur.

In addition to the routine CLIA certification surveys, announced or unannounced investigations/ surveys may be conducted by CMS or CMS' agents at any time to address complaints or other non-compliance issues. These investigations/surveys may well identify violations that may not have surfaced during a routine survey using random sampling, but for which the laboratory and its director will still be held responsible.

Instructions for Submitting the Laboratory's Response

All responses as well as any future correspondence pertaining to this survey should be sent to:

Karen Fuller, Manager
State Oversight and CLIA Branch
Division of Survey and Certification
Centers for Medicare & Medicaid Services
90 7th Street, Suite 5-300 (5W)
San Francisco, CA 94103-6707

A copy of any response the laboratory makes to CMS' San Francisco Regional Office must also be sent to CMS' Central Office at the following address:

FOIA Confidential Treatment Requested by Theranos TS-0917885
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Division of Laboratory Services
Survey and Certification Group (SCG)
Center for Clinical Standards and Quality (CCSQ)
Centers for Medicare & Medicaid Services
7500 Security Blvd – Mail Stop C2-21-16
Baltimore, MD 21244
Attention: Sarah Bennett

If you have questions regarding this letter, please contact Gary Yamamoto of my staff at (415) 744-3738.

Sincerely,

Karen Fuller

Karen Fuller, Manager
State Oversight and CLIA Branch
Division of Survey and Certification

Enclosure: Form CMS-2567, Statement of Deficiencies

cc: California Department of Public Health, Laboratory Field Services

CMS, Central Office

FOIA Confidential Treatment Requested by Theranos TS-0917886

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EXHIBIT 18

PRINTED: 01/25/2016
FORM APPROVED
OMB NO. 0938-0391

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	05D2025714	A. BUILDING _____ B. WING _____	11/20/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
THERANOS INC	7333 GATEWAY BLVD NEWARK, CA 94560

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
D5481	493.1256(f)(g) CONTROL PROCEDURES (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: 1. Based on review of the prothrombin time/international normalized ratio (PT/INR) procedure, quality control (QC) records, patient results and interview with the general supervisor, the laboratory failed to ensure that the QC for PT/INR was acceptable prior to reporting patient results from April 2015 through September 2015. Findings include: a. CL SOP-10001 Revision A, "Measuring Prothrombin Time-Innovin (PT on the Siemens BCS XP Instrument" stated on page 6, section 8.6 that if control values are outside of the determined range, the controls, reagents and instrument performance should be checked and that identification and correction of the problem shoud be documented prior to reporting patient results. b. QC records for Citrol 3 (Lot number 548425) were reviewed from 4/1/15 through 9/23/15. c. The general supervisor stated that QC was acceptable if the values were +/- 2 SD from the	D5481		

FOIA Confidential Treatment Requested by Theranos TS-0917922

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	05D2025714	A. BUILDING _____ B. WING _____	11/20/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
THERANOS INC	7333 GATEWAY BLVD NEWARK, CA 94560

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
D5481	Continued From page 36 mean. d. On 9/7/15, Citrol 3 was run seven times without obtaining an acceptable QC value. e. On 9/8/15, Citrol 3 was run twelve times without obtaining an acceptable QC value. f. On 25 of 32 days, Citrol 3 was not rerun when the QC value was greater than - 2 SD. g. On 5/15/15, 8/13/15, 8/21/15 and 9/10/15, Citrol 3 was run twice. All QC results were unacceptable. h. The Rule Check report revealed that 13 of 13 QC values in April 2015, 2 of 17 in May 2015, 7 of 7 in June 2015, 13 of 13 in July 2015, 16 of 16 in August, and 24 of 24 during September 1-16, 2015 showed rule violation messages related to Citrol 3. i. 81 patients were reported from 4/1/15 through 9/16/15. 2. Based on review of the quality control (QC) procedure, QC records, and raw data from patient test runs and interview with the general supervisor, the laboratory failed to ensure that the QC was acceptable for the Theranos Proprietary System (TPS) prior to reporting patient test results: Findings include: a. CL SOP-15026 Revision A, "Edison 3.5 Theranos System Daily QC Procedures", stated the following in section 10.1.1: "...For any single Edison instrument, reject QC if either level is greater than 2 SD or if either level falls on the same side of the mean for 10 consecutive days."	D5481		

FOIA Confidential Treatment Requested by Theranos TS-0917923

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	05D2025714	A. BUILDING _____ B. WING _____	11/20/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
THERANOS INC	7333 GATEWAY BLVD NEWARK, CA 94560

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
D5481	Continued From page 37 b. Section 11.1.1 of CL SOP-15026 Revision A further stated that "Daily QC automatically expires 24 hours after use." c. The general supervisor stated that when the QC was unacceptable, the TPS device locked out patient testing for 24 hours or until the QC was acceptable and if the QC was unacceptable another device would be used for testing. d. QC records for Sex Hormone Binding Globulin (SHBG) showed that on Device E001025 QC Level 2's (QC2) 24 hour expiration was on 8/14/14 at 18:54 and was not run again until 8/15/14 at 00:05. Patient data showed that patient Accession #94389 was run on 8/14/14 at 19:09. e. QC records for SHBG showed that on Device E001025 QC Level 1's (QC1) 24 hour expiration was on 8/20/14 at 17:43 and was not run again until 8/21/14 at 17:50. Patient data showed that patient Accession #95403 was run on 8/20/14 at 19:08. f. QC records for SHBG showed that on Device E001036 QC1 was not run again until 11/1/14 at 22:15. Patient data showed that patient Accession #112807 was run on 11/1/14 at 00:02. g. QC records for Vitamin B12 (VB12) showed that on Device E000027 QC1 was run on 8/16/14 at 06:16 and failed. QC1 was next run 8/17/14 at 09:10 and passed. QC2 was not run on 8/15/14 or 8/16/14. Patient data showed that patient Accession #94598 was run on 8/16/14 at 00:48. h. QC records for VB12 showed that on Device	D5481		

FOIA Confidential Treatment Requested by Theranos TS-0917924

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	05D2025714	A. BUILDING _____ B. WING _____	11/20/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
THERANOS INC	7333 GATEWAY BLVD NEWARK, CA 94560

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
D5481	Continued From page 38 E000027 QC1 was run on 8/16/14 at 06:16 and failed. QC1 was next run 8/17/14 at 09:10 and passed. QC2 was not run on 8/15/14 or 8/16/14. Patient data showed that patient Accession #94598 was run on 8/16/14 at 00:48. i. QC records for VB12 showed that on Device E000027 QC2 24 hour expiration was on 8/19/14 at 08:00 and was not run again until 8/20/14 at 21:05. Patient data showed that 3 patients (Accession #s 95411, 95462, 95543) were run on 8/20/14 between 12:33 and 17:52. j. QC records for VB12 showed that on Device E000027 QC2 24 hour expiration was on 8/22/14 at 17:38 and was not run again until 8/23/14 at 21:05. Patient data showed that 2 patients (Accession #s 95984, 96106) were run on 8/22/14 at 18:56 and 21:21. k. QC records for VB12 showed that on Device E000027 QC1's 24 hour expiration was on 8/24/14 at 16:43 and was not run again until 8/25/14 at 07:59. QC2 24 hour expiration was on 8/24/14 at 21:05 and was not run again until 8/25/14 at 12:23. Patient data showed that 3 patients (Accession #s 96327, 96250, 96371) were run on 8/24/14 between 17:15 and 21:36. l. QC records for VB12 showed that on Device E000037 QC1 had a "10x warning" message in the QC Pass/Fail Status column on 2/25/15 at 20:29 and again on 2/26/15 at 20:22. QC2 had a "10x warning" message in the QC Pass/Fail Status column on 2/25/15 at 22:11 and again on 2/26/15 at 22:04. QC1 passed on 2/27/15 at 22:54 and QC2 was run and passed on 2/28/15 at 00:27. Patient data showed that 7 patients (Accession #s 146275, 146391, 146651, 146852,	D5481		

FOIA Confidential Treatment Requested by Theranos TS-0917925

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	05D2025714	A. BUILDING _____ B. WING _____	11/20/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
THERANOS INC	7333 GATEWAY BLVD NEWARK, CA 94560

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
D5481	Continued From page 39 147149, 146596, 146898) were run between 2/26/15 and 2/27/15 during the time the laboratory had a 10x warning. m. QC records for VB12 showed that on Device E001000 QC1's 24 hour expiration was on 1/25/15 at 21:58 and was not run again until 1/28/15 at 2140. QC2 24 hour expiration was on 1/26/15 at 02:22 and was not run again until 1/28/15 at 23:19. Patient data showed that 5 patients (Accession #s 136351, 136139,136386, 136897, 135548) were run between 1/27/15 at 1359 and 1/28/15 at 11:50. n. QC records for Vitamin D, 25-OH (VitD) showed that on Device E001059 QC1's 24 hour expiration was on 7/6/14 at 14:11 and was not run again until 7/7/15 at 08:04. Patient data showed that Accession #88699 was run on 7/6/14 at 14:31. o. Levey-Jennings charts revealed that SHBG Device E000026 QC1 had 13 consecutive days and QC2 had 15 consecutive days that the results were at least 2 standard deviations (SDs) below the mean from 9/30/14 through 10/29/14. p. Levey-Jennings charts revealed that SHBG Device E001007 QC1 had 19 consecutive days that the results were at least 2 SDs below the mean from 3/31/15 through 4/29/15. q. Levey-Jennings charts revealed that VitD Device E001059 QC1 had 15 consecutive days that the results were at least 2 SDs above the mean from 6/30/15 through 7/25/14. r. Levey-Jennings charts revealed that Total T3 (TT3) Device E000195 QC1 had 11 consecutive	D5481		

FOIA Confidential Treatment Requested by Theranos TS-0917926

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	05D2025714	A. BUILDING _____ B. WING _____	11/20/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
THERANOS INC	7333 GATEWAY BLVD NEWARK, CA 94560

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
D5481	Continued From page 40 days that the results were at least 2 SDs above the mean from 1/3/15 through 1/29/15. s. Levey-Jennings charts revealed that TT3 Device E001032 QC1 had 113 consecutive days and QC2 had 12 consecutive days that the results were at least 2 SDs above the mean from 7/9/14 through 7/25/14. t. Levey-Jennings charts revealed that VB12 Device E000187 QC1 had 14 consecutive days and QC2 had 12 consecutive days that the results were at least 2 SDs above the mean from 2/10/14 through 2/27/14.	D5481		
D5775 400B	493.1281(a)(c) COMPARISON OF TEST RESULTS (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced bv:	D5775		

FOIA Confidential Treatment Requested by Theranos TS-0917927

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	05D2025714	A. BUILDING _____ B. WING _____	11/20/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
THERANOS INC	7333 GATEWAY BLVD NEWARK, CA 94560

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
D5775	Continued From page 41	D5775		

2. Based on review of documentation, the laboratory failed to have a system that twice a year evaluated and defined the relationship between the Theranos Proprietary System (TPS) to a predicate instrument. Findings include:'

a. Undated documentation provided by the laboratory revealed a comparison study between the Theranos Proprietary System (TPS) (i.e., Edison) and a predicate device (Immulite, Centaur, or Liaison) for Sex Hormone Binding Globulin (SHBG), Total T3 (TT3), Vitamin D (VitD) and Vitamin B12 (VB12).

b. The method comparison documentation showed that the following devices (i.e., readers) E000026, E001025 and E001036 were used for SHBG comparison testing. SHBG testing occurred from 7/28/14 through 6/25/15.

c. Quality control (QC) monthly reports revealed that seven devices were used for SHBG from February 2015 through June 2015 but only three devices were included in the comparison study.

d. QC and patient result documentation for SHBG also revealed that devices E000040, E001007 and E001035 were used for patient

FOIA Confidential Treatment Requested by Theranos TS-0917928

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	05D2025714	A. BUILDING _____ B. WING _____	11/20/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
THERANOS INC	7333 GATEWAY BLVD NEWARK, CA 94560

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
D5775	Continued From page 42 testing and were not included in the comparison study. e. The method comparison documentation showed that the following devices E000162, E000187, E00195, E001011, E001032, and E001049 were used for TT3 testing. TT3 testing occurred from 2/2/14 through 2/4/15. f. The method comparison documentation showed that the following devices E000053, E000072, E00101, E0001157, E001007, E001043, and E001059 were used for VitD testing. VitD testing occurred from 11/6/13 through 3/10/15. g. Quality control (QC) monthly reports revealed that twelve devices were used for VitD in February 2015 and eighteen devices were used from March 2015 through April 2015 but only seven devices were included in the comparison study. h. QC and patient result documentation for VitD also revealed that device E001059 was used for patient testing and was not included in the comparison study. i. The method comparison documentation showed that the following devices E000053, E000072, E00101, E0001157, E001007, E001043, and E001059 were used for VB12 testing. VB12 testing occurred from 8/12/14 through 3/6/15. j. Quality control (QC) monthly reports revealed that twelve devices were used for VB12 in October 2014 and February 2015 through April 2015 but only eleven devices were included in the	D5775		

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
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D5775	Continued From page 43 comparison study.	D5775		

FOIA Confidential Treatment Requested by Theranos TS-0917930

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
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D5791	493.1289(a)(c) ANALYTIC SYSTEMS QUALITY ASSESSMENT (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in	D5791		

FOIA Confidential Treatment Requested by Theranos TS-0917933

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
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D5791	Continued From page 47 §§493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by:	D5791		

FOIA Confidential Treatment Requested by Theranos TS-0917934

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
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D5791		D5791		

2. Based on review of Quality Control (QC) data and Monthly QC Reports, the laboratory failed to have a quality assessment (QA) procedure to identify and correct problem with the QC values for the Theranos Proprietary System (TPS) when precision did not meet the laboratory's requirement for precision. Findings include:

a. CL PLN-14003 Revision A, "Master Validation Plan for Routine Chemistry Assays on Theranos

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
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D5791	Continued From page 49 Devices" in section 13.4.5 requires the %CV of replicates to be not more than 15% (20% at the lower and upper limits of detection). b. QC results were reviewed from June 2014 through November 2014 and January through February 2015 for Vitamin B12 (VB12), Vitamin D (VitD), and Sex Hormone Binding Globuin (SHBG) which were used for patient testing on the TPS devices. c. VB12 QC Level 1 and Level 3 (QC1 and QC3) on Device E000110 revealed the following %CV (coefficient of variation): 34.3% and 48.5%, respectively, from 1/5/15 through 1/30/15. d. VB12 QC1 and QC3 on Device E001085 revealed the following %CVs: 52.5% and 35.2%, respectively, from 1/5/15 through 1/30/15. e. VB12 QC1 and QC3 on Device E001102 revealed the following %CVs: 39.0% and 20.0%, respectively, from 2/10/15 through 2/27/15. f. VB12 QC1 and QC3 on Device E001000 revealed the following %CVs: 34.7% and 39.9%, respectively, from 1/2/15 through 1/31/15. g. VB12 QC1 and QC3 on Device E001102 revealed the following %CVs: 39.0% and 20.0%, respectively, from 2/10/15 through 2/27/15. h. VitD QC Level 1 and Level 2 (QC1 and QC2) on Device E000053 revealed the following %CVs: 63.8% and 26.4%, respectively, from 8/21/14 through 8/30/14. i. VitD QC1 and QC2 on Device E001059 revealed the following %CVs: 18.7% and 18.7%,	D5791		

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
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D5791	Continued From page 50 respectively, from 6/29/14 through 7/24/14. j. VitD QC1 and QC2 on Device E001043 revealed the following %CVs: 25.2% and 31.9%, respectively, from 6/29/14 through 7/25/14. k. SHBG QC1 on Device E001026 revealed the following %CV: 18.9% from 9/30/14 through 11/5/14. l. SHBG QC1 on Device E001025 revealed the following %CV: 21.2% from 7/31/14 through 8/28/14. 3. Based on review of Quality Assessment (QA) documentation and QA procedures, the laboratory failed to have a quality assessment (QA) procedure established to identify and correct problems with the Quality Control (QC) program for the Theranos Proprietary System (TPS) . Findings include: a. Monthly QC reports were reviewed for July 2014, October 2014, and February through June 2015. b. All reports were signed by the laboratory director (LD) on 9/19/15, except the March 2015 report was signed by the LD on 11/19/15. c. The total percentage of QC values greater than 2 standard deviations (SDs) was reviewed by the surveyor. d. The July 2014 report indicated in the summary that 2179 controls had been run on the "Edison**" devices; however, the specific report on the "Edison**" device showed that only 1618 were run on all tests and all devices.	D5791		

FOIA Confidential Treatment Requested by Theranos TS-0917937

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
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D5791	Continued From page 51 e. In July 2014, the data revealed the following tests showed percentage of QC samples with more than 15% of values greater than 2 SD: Testosterone (TST) (28%), Total T4 (TT4) (21%), VitD (28%). Overall 16% of QC samples on all tests on all devices had values greater than 2 SDs. f. In October 2014, the data revealed the following tests showed percentage of QC samples with more than 15% of values greater than 2 SD: Estradiol (EST) (33%), Free T4 (FT4) (19%), Prolactin (PRLN) (47%), SHBG (45%), Thyroid Stimulating Hormone (TSH) (26%), TST (45%), Total T3 (TT3) (32%), TT4 (28%), VitD (19%), VB12 (46%). Overall 29% of QC samples on all tests on all devices had values greater than 2 SDs. g. In February 2015, the data revealed the following tests showed percentage of QC samples with more than 15% of values greater than 2 SD: FT4 (26%), SHBG (87%), TT3 (33%), VitD (24%), VB12 (20%). Overall 24% of QC samples on all tests on all devices had values greater than 2 SDs. h. In March 2015, the data revealed the following tests showed percentage of QC samples with more than 15% of values greater than 2 SD: SHBG (42%), TSH (20%). Overall 20% of QC samples on all tests on all devices had values greater than 2 SDs. i. In April 2015, the data revealed the following tests showed percentage of QC samples with more than 15% of values greater than 2 SD: SHBG (16%), total Prostate Specific Antigen	D5791		

FOIA Confidential Treatment Requested by Theranos TS-0917938

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
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D5791	Continued From page 52 (tPSA) (22%), VB12 (60%). Overall 21% of QC samples on all tests on all devices had values greater than 2 SDs. j. In May 2015, the data revealed the following tests showed percentage of QC samples with more than 15% of values greater than 2 SD: SHBG (34%), tPSA (22%). Overall 26% of QC samples on all tests on all devices had values greater than 2 SDs. k. In June 2015, the data revealed the following tests showed percentage of QC samples with more than 15% of values greater than 2 SD: SHBG (23%). Overall 14% of QC samples on all tests on all devices had values greater than 2 SDs.	D5791		

FOIA Confidential Treatment Requested by Theranos TS-0917939

EXHIBIT 19

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
Western Division of Survey and Certification
San Francisco Regional Office
90 7th Street, Suite 5-300 (5W)
San Francisco, CA 94103-6707

CENTERS FOR MEDICARE & MEDICAID SERVICES

Refer to: WDSC- GKY

IMPORTANT NOTICE – PLEASE READ CAREFULLY

January 25, 2016

Sunil Dhawan, M.D., Director
Theranos, Inc.
7333 Gateway Boulevard
Newark, CA 94560

CLIA Number: 05D2025714

RE: CONDITION LEVEL DEFICIENCIES – IMMEDIATE JEOPARDY

Dear Dr. Dhawan:

In order for a laboratory to perform testing under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), Public Law 100-578, it must comply with all CLIA requirements. These requirements are found in section 353 of the Public Health Service Act (42 U.S.C. 263a) and 42 Code of Federal Regulations, Part 493 (42 CFR 493). Federal regulations require onsite surveys to determine whether or not a laboratory is in compliance with the applicable regulations. Compliance with these regulations is a condition of certification for the CLIA program.

The Centers for Medicare & Medicaid Services (CMS) conducted a CLIA recertification and complaint survey of the laboratory. The onsite survey was completed on November 20, 2015. However, the survey concluded with the receipt of critical information received from the laboratory on December 23, 2015. As a result of the survey, it was determined that your facility is not in compliance with all of the Conditions required for certification in the CLIA program. In addition, based on the Condition-level requirement at 42 C.F.R. § 493.1215, Hematology, it was determined that the deficient practices of the laboratory pose immediate jeopardy to patient health and safety. (Immediate jeopardy is defined by the CLIA regulations as a situation in which immediate corrective action is necessary because the laboratory's non-compliance with one or more Condition-level requirements has already caused, is causing, or is likely to cause, at any time, serious injury or harm, or death, to individuals served by the laboratory or to the health and safety of the general public.) Specifically, the following Conditions were not met:

D5024: 42 C.F.R. § 493.1215	Condition: Hematology;
D5400: 42 C.F.R. § 493.1250	Condition: Analytic systems;
D6076: 42 C.F.R. § 493.1441	Condition: Laboratories performing high complexity testing; laboratory director;
D6108: 42 C.F.R. § 493.1447	Condition: Laboratories performing high complexity testing; technical supervisor; and,

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D6168: 42 C.F.R. § 493.1487 Condition: Laboratories performing high complexity testing; testing personnel.

In addition, other standards were also found to be not met. Enclosed is Form CMS-2567, Statement of Deficiencies, listing all the deficiencies found during the survey.

When a laboratory's deficiencies pose immediate jeopardy, CMS requires the laboratory to take immediate action to remove the jeopardy and come into Condition-level compliance. Laboratories that do not meet the Condition-level requirements of CLIA may not be certified to perform laboratory testing under the CLIA program.

The laboratory has 10 CALENDAR DAYS from the date of receipt of this notice to provide CMS' Central Office and San Francisco Regional Office with a credible allegation of compliance and acceptable evidence of correction documenting that the immediate jeopardy has been removed and that action has been taken to correct all of the Condition-level deficiencies in question.

Please document the laboratory's allegation of compliance using the enclosed Form CMS-2567, Statement of Deficiencies, in the columns labeled "Provider Plan of Correction" and "Completion Date" located on the right side of the form, keying your responses to the deficiencies on the left. The laboratory director must sign, date and return the completed Form CMS-2567 documented with a credible allegation of compliance WITHIN 10 CALENDAR DAYS from the date of receipt of this notice. You must also submit documented evidence that verifies that the corrections were made. (Your allegation of compliance will be included in the public record of the inspection.)

For your information, a credible allegation of compliance is a statement or documentation that is:

1) Made by a representative of a laboratory with a history of having maintained a commitment to compliance and taking corrective action when required;

2) Realistic in terms of the possibility of the corrective action being accomplished between the date of the survey and the date of the allegation; and

3) Indicates resolution of the problems.

In addition, acceptable evidence of correction must include:

1) Documentation showing what corrective action(s) have been taken for patients found to have been affected by the deficient practice;

2) How the laboratory has identified other patients having the potential to be affected by the same deficient practice and what corrective action(s) has been taken;

3) What measure has been put into place or what systemic changes have been made to ensure that the deficient practice does not recur; and

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4) How the corrective action(s) are being monitored to ensure the deficient practice does not recur.

If the laboratory submits a credible allegation of compliance and acceptable evidence of correction that the laboratory has removed jeopardy and come into Condition-level compliance, and we are able to verify compliance with all CLIA requirements through a follow-up survey, sanctions will not be imposed. If the laboratory does not submit a credible allegation of compliance and acceptable evidence of correction, we will not conduct a follow-up survey.

If jeopardy is not removed and the laboratory does not come into Condition-level compliance, CMS will take sanction action(s) against the laboratory's CLIA certificate. If necessary, we will advise the laboratory in writing of the sanction(s) to be imposed and/or enforcement action(s) that will be taken. These sanctions may include alternative sanctions (Civil Money Penalty of up to $10,000 per day of non-compliance pursuant to 42 C.F.R. §493.1834, Directed Plan of Correction pursuant to 42 C.F.R. § 493.1832, and/or State Onsite Monitoring pursuant to 42 C.F.R. § 493.1836) and principal sanctions (suspension, limitation and/or revocation of the laboratory's CLIA certificate and cancellation of the laboratory's approval for Medicare payments pursuant to 42 C.F.R. § 493.1814).

Please note that the routine survey takes an overview of the laboratory through random sampling. By its nature, the routine survey may not find every violation that the laboratory may have committed. It remains the responsibility of the laboratory and its director to ensure that the laboratory is at all times following all CLIA requirements, to identify any problems in the laboratory and take corrective action specific to the problems, and to institute appropriate quality assurance measures to ensure that the deficient practices do not recur.

In addition to the routine CLIA certification surveys, announced or unannounced investigations/ surveys may be conducted by CMS or CMS' agents at any time to address complaints or other non-compliance issues. These investigations/surveys may well identify violations that may not have surfaced during a routine survey using random sampling, but for which the laboratory and its director will still be held responsible.

Instructions for Submitting the Laboratory's Response

All responses as well as any future correspondence pertaining to this survey should be sent to:

Karen Fuller, Manager
State Oversight and CLIA Branch
Division of Survey and Certification
Centers for Medicare & Medicaid Services
90 7th Street, Suite 5-300 (5W)
San Francisco, CA 94103-6707

A copy of any response the laboratory makes to CMS' San Francisco Regional Office must also be sent to CMS' Central Office at the following address:

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Trial Exh. 4621 Page 0003

Division of Laboratory Services
Survey and Certification Group (SCG)
Center for Clinical Standards and Quality (CCSQ)
Centers for Medicare & Medicaid Services
7500 Security Blvd – Mail Stop C2-21-16
Baltimore, MD 21244
Attention: Sarah Bennett

If you have questions regarding this letter, please contact Gary Yamamoto of my staff at (415) 744-3738.

Sincerely,

Karen Fuller

Karen Fuller, Manager
State Oversight and CLIA Branch
Division of Survey and Certification

Enclosure: Form CMS-2567, Statement of Deficiencies

cc: California Department of Public Health, Laboratory Field Services

CMS, Central Office

FOIA Confidential Treatment Requested by Theranos TS-0917886
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EXHIBIT 20

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
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D5481	493.1256(f)(g) CONTROL PROCEDURES (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: 1. Based on review of the prothrombin time/international normalized ratio (PT/INR) procedure, quality control (QC) records, patient results and interview with the general supervisor, the laboratory failed to ensure that the QC for PT/INR was acceptable prior to reporting patient results from April 2015 through September 2015. Findings include: a. CL SOP-10001 Revision A, "Measuring Prothrombin Time-Innovin (PT on the Siemens BCS XP Instrument" stated on page 6, section 8.6 that if control values are outside of the determined range, the controls, reagents and instrument performance should be checked and that identification and correction of the problem shoud be documented prior to reporting patient results. b. QC records for Citrol 3 (Lot number 548425) were reviewed from 4/1/15 through 9/23/15. c. The general supervisor stated that QC was acceptable if the values were +/- 2 SD from the	D5481		

FOIA Confidential Treatment Requested by Theranos TS-0917922

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
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D5481	Continued From page 36 mean. d. On 9/7/15, Citrol 3 was run seven times without obtaining an acceptable QC value. e. On 9/8/15, Citrol 3 was run twelve times without obtaining an acceptable QC value. f. On 25 of 32 days, Citrol 3 was not rerun when the QC value was greater than - 2 SD. g. On 5/15/15, 8/13/15, 8/21/15 and 9/10/15, Citrol 3 was run twice. All QC results were unacceptable. h. The Rule Check report revealed that 13 of 13 QC values in April 2015, 2 of 17 in May 2015, 7 of 7 in June 2015, 13 of 13 in July 2015, 16 of 16 in August, and 24 of 24 during September 1-16, 2015 showed rule violation messages related to Citrol 3. i. 81 patients were reported from 4/1/15 through 9/16/15. 2. Based on review of the quality control (QC) procedure, QC records, and raw data from patient test runs and interview with the general supervisor, the laboratory failed to ensure that the QC was acceptable for the Theranos Proprietary System (TPS) prior to reporting patient test results: Findings include: a. CL SOP-15026 Revision A, "Edison 3.5 Theranos System Daily QC Procedures", stated the following in section 10.1.1: "...For any single Edison instrument, reject QC if either level is greater than 2 SD or if either level falls on the same side of the mean for 10 consecutive days."	D5481		

FOIA Confidential Treatment Requested by Theranos TS-0917923

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
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D5481	Continued From page 37 b. Section 11.1.1 of CL SOP-15026 Revision A further stated that "Daily QC automatically expires 24 hours after use." c. The general supervisor stated that when the QC was unacceptable, the TPS device locked out patient testing for 24 hours or until the QC was acceptable and if the QC was unacceptable another device would be used for testing. d. QC records for Sex Hormone Binding Globulin (SHBG) showed that on Device E001025 QC Level 2's (QC2) 24 hour expiration was on 8/14/14 at 18:54 and was not run again until 8/15/14 at 00:05. Patient data showed that patient Accession #94389 was run on 8/14/14 at 19:09. e. QC records for SHBG showed that on Device E001025 QC Level 1's (QC1) 24 hour expiration was on 8/20/14 at 17:43 and was not run again until 8/21/14 at 17:50. Patient data showed that patient Accession #95403 was run on 8/20/14 at 19:08. f. QC records for SHBG showed that on Device E001036 QC1 was not run again until 11/1/14 at 22:15. Patient data showed that patient Accession #112807 was run on 11/1/14 at 00:02. g. QC records for Vitamin B12 (VB12) showed that on Device E000027 QC1 was run on 8/16/14 at 06:16 and failed. QC1 was next run 8/17/14 at 09:10 and passed. QC2 was not run on 8/15/14 or 8/16/14. Patient data showed that patient Accession #94598 was run on 8/16/14 at 00:48. h. QC records for VB12 showed that on Device	D5481		

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(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
D5481	Continued From page 38 E000027 QC1 was run on 8/16/14 at 06:16 and failed. QC1 was next run 8/17/14 at 09:10 and passed. QC2 was not run on 8/15/14 or 8/16/14. Patient data showed that patient Accession #94598 was run on 8/16/14 at 00:48. i. QC records for VB12 showed that on Device E000027 QC2 24 hour expiration was on 8/19/14 at 08:00 and was not run again until 8/20/14 at 21:05. Patient data showed that 3 patients (Accession #s 95411, 95462, 95543) were run on 8/20/14 between 12:33 and 17:52. j. QC records for VB12 showed that on Device E000027 QC2 24 hour expiration was on 8/22/14 at 17:38 and was not run again until 8/23/14 at 21:05. Patient data showed that 2 patients (Accession #s 95984, 96106) were run on 8/22/14 at 18:56 and 21:21. k. QC records for VB12 showed that on Device E000027 QC1's 24 hour expiration was on 8/24/14 at 16:43 and was not run again until 8/25/14 at 07:59. QC2 24 hour expiration was on 8/24/14 at 21:05 and was not run again until 8/25/14 at 12:23. Patient data showed that 3 patients (Accession #s 96327, 96250, 96371) were run on 8/24/14 between 17:15 and 21:36. l. QC records for VB12 showed that on Device E000037 QC1 had a "10x warning" message in the QC Pass/Fail Status column on 2/25/15 at 20:29 and again on 2/26/15 at 20:22. QC2 had a "10x warning" message in the QC Pass/Fail Status column on 2/25/15 at 22:11 and again on 2/26/15 at 22:04. QC1 passed on 2/27/15 at 22:54 and QC2 was run and passed on 2/28/15 at 00:27. Patient data showed that 7 patients (Accession #s 146275, 146391, 146651, 146852,	D5481		

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D5481	Continued From page 39 147149, 146596, 146898) were run between 2/26/15 and 2/27/15 during the time the laboratory had a 10x warning. m. QC records for VB12 showed that on Device E001000 QC1's 24 hour expiration was on 1/25/15 at 21:58 and was not run again until 1/28/15 at 2140. QC2 24 hour expiration was on 1/26/15 at 02:22 and was not run again until 1/28/15 at 23:19. Patient data showed that 5 patients (Accession #s 136351, 136139,136386, 136897, 135548) were run between 1/27/15 at 1359 and 1/28/15 at 11:50. n. QC records for Vitamin D, 25-OH (VitD) showed that on Device E001059 QC1's 24 hour expiration was on 7/6/14 at 14:11 and was not run again until 7/7/15 at 08:04. Patient data showed that Accession #88699 was run on 7/6/14 at 14:31. o. Levey-Jennings charts revealed that SHBG Device E000026 QC1 had 13 consecutive days and QC2 had 15 consecutive days that the results were at least 2 standard deviations (SDs) below the mean from 9/30/14 through 10/29/14. p. Levey-Jennings charts revealed that SHBG Device E001007 QC1 had 19 consecutive days that the results were at least 2 SDs below the mean from 3/31/15 through 4/29/15. q. Levey-Jennings charts revealed that VitD Device E001059 QC1 had 15 consecutive days that the results were at least 2 SDs above the mean from 6/30/15 through 7/25/14. r. Levey-Jennings charts revealed that Total T3 (TT3) Device E000195 QC1 had 11 consecutive	D5481		

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(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
D5481	Continued From page 40 days that the results were at least 2 SDs above the mean from 1/3/15 through 1/29/15. s. Levey-Jennings charts revealed that TT3 Device E001032 QC1 had 113 consecutive days and QC2 had 12 consecutive days that the results were at least 2 SDs above the mean from 7/9/14 through 7/25/14. t. Levey-Jennings charts revealed that VB12 Device E000187 QC1 had 14 consecutive days and QC2 had 12 consecutive days that the results were at least 2 SDs above the mean from 2/10/14 through 2/27/14.	D5481		
D5775 400B	493.1281(a)(c) COMPARISON OF TEST RESULTS (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by:	D5775		

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
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D5775	Continued From page 41	D5775		

2. Based on review of documentation, the laboratory failed to have a system that twice a year evaluated and defined the relationship between the Theranos Proprietary System (TPS) to a predicate instrument. Findings include:

a. Undated documentation provided by the laboratory revealed a comparison study between the Theranos Proprietary System (TPS) (i.e., Edison) and a predicate device (Immulite, Centaur, or Liaison) for Sex Hormone Binding Globulin (SHBG), Total T3 (TT3), Vitamin D (VitD) and Vitamin B12 (VB12).

b. The method comparison documentation showed that the following devices (i.e., readers) E000026, E001025 and E001036 were used for SHBG comparison testing. SHBG testing occurred from 7/28/14 through 6/25/15.

c. Quality control (QC) monthly reports revealed that seven devices were used for SHBG from February 2015 through June 2015 but only three devices were included in the comparison study.

d. QC and patient result documentation for SHBG also revealed that devices E000040, E001007 and E001035 were used for patient

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D5775	Continued From page 42 testing and were not included in the comparison study. e. The method comparison documentation showed that the following devices E000162, E000187, E00195, E001011, E001032, and E001049 were used for TT3 testing. TT3 testing occurred from 2/2/14 through 2/4/15. f. The method comparison documentation showed that the following devices E000053, E000072, E00101, E0001157, E001007, E001043, and E001059 were used for VitD testing. VitD testing occurred from 11/6/13 through 3/10/15. g. Quality control (QC) monthly reports revealed that twelve devices were used for VitD in February 2015 and eighteen devices were used from March 2015 through April 2015 but only seven devices were included in the comparison study. h. QC and patient result documentation for VitD also revealed that device E001059 was used for patient testing and was not included in the comparison study. i. The method comparison documentation showed that the following devices E000053, E000072, E00101, E0001157, E001007, E001043, and E001059 were used for VB12 testing. VB12 testing occurred from 8/12/14 through 3/6/15. j. Quality control (QC) monthly reports revealed that twelve devices were used for VB12 in October 2014 and February 2015 through April 2015 but only eleven devices were included in the	D5775		

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D5775	Continued From page 43 comparison study.	D5775		

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OMB NO. 0938-0391

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D5791	493.1289(a)(c) ANALYTIC SYSTEMS QUALITY ASSESSMENT (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in	D5791		

FOIA Confidential Treatment Requested by Theranos TS-0917933

DEPARTMENT OF HEALTH AND HUMAN SERVICES
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D5791	Continued From page 47 §§493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by:	D5791		

FOIA Confidential Treatment Requested by Theranos TS-0917934

DEPARTMENT OF HEALTH AND HUMAN SERVICES
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D5791		D5791		

2. Based on review of Quality Control (QC) data and Monthly QC Reports, the laboratory failed to have a quality assessment (QA) procedure to identify and correct problem with the QC values for the Theranos Proprietary System (TPS) when precision did not meet the laboratory's requirement for precision. Findings include:

a. CL PLN-14003 Revision A, "Master Validation Plan for Routine Chemistry Assays on Theranos

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D5791	Continued From page 49 Devices" in section 13.4.5 requires the %CV of replicates to be not more than 15% (20% at the lower and upper limits of detection). b. QC results were reviewed from June 2014 through November 2014 and January through February 2015 for Vitamin B12 (VB12), Vitamin D (VitD), and Sex Hormone Binding Globuin (SHBG) which were used for patient testing on the TPS devices. c. VB12 QC Level 1 and Level 3 (QC1 and QC3) on Device E000110 revealed the following %CV (coefficient of variation): 34.3% and 48.5%, respectively, from 1/5/15 through 1/30/15. d. VB12 QC1 and QC3 on Device E001085 revealed the following %CVs: 52.5% and 35.2%, respectively, from 1/5/15 through 1/30/15. e. VB12 QC1 and QC3 on Device E001102 revealed the following %CVs: 39.0% and 20.0%, respectively, from 2/10/15 through 2/27/15. f. VB12 QC1 and QC3 on Device E001000 revealed the following %CVs: 34.7% and 39.9%, respectively, from 1/2/15 through 1/31/15. g. VB12 QC1 and QC3 on Device E001102 revealed the following %CVs: 39.0% and 20.0%, respectively, from 2/10/15 through 2/27/15. h. VitD QC Level 1 and Level 2 (QC1 and QC2) on Device E000053 revealed the following %CVs: 63.8% and 26.4%, respectively, from 8/21/14 through 8/30/14. i. VitD QC1 and QC2 on Device E001059 revealed the following %CVs: 18.7% and 18.7%,	D5791		

FOIA Confidential Treatment Requested by Theranos TS-0917936

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D5791	Continued From page 50 respectively, from 6/29/14 through 7/24/14. j. VitD QC1 and QC2 on Device E001043 revealed the following %CVs: 25.2% and 31.9%, respectively, from 6/29/14 through 7/25/14. k. SHBG QC1 on Device E001026 revealed the following %CV: 18.9% from 9/30/14 through 11/5/14. l. SHBG QC1 on Device E001025 revealed the following %CV: 21.2% from 7/31/14 through 8/28/14. 3. Based on review of Quality Assessment (QA) documentation and QA procedures, the laboratory failed to have a quality assessment (QA) procedure established to identify and correct problems with the Quality Control (QC) program for the Theranos Proprietary System (TPS) . Findings include: a. Monthly QC reports were reviewed for July 2014, October 2014, and February through June 2015. b. All reports were signed by the laboratory director (LD) on 9/19/15, except the March 2015 report was signed by the LD on 11/19/15. c. The total percentage of QC values greater than 2 standard deviations (SDs) was reviewed by the surveyor. d. The July 2014 report indicated in the summary that 2179 controls had been run on the "Edison**" devices; however, the specific report on the "Edison**" device showed that only 1618 were run on all tests and all devices.	D5791		

FOIA Confidential Treatment Requested by Theranos TS-0917937

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D5791	Continued From page 51 e. In July 2014, the data revealed the following tests showed percentage of QC samples with more than 15% of values greater than 2 SD: Testosterone (TST) (28%), Total T4 (TT4) (21%), VitD (28%). Overall 16% of QC samples on all tests on all devices had values greater than 2 SDs. f. In October 2014, the data revealed the following tests showed percentage of QC samples with more than 15% of values greater than 2 SD: Estradiol (EST) (33%), Free T4 (FT4) (19%), Prolactin (PRLN) (47%), SHBG (45%), Thyroid Stimulating Hormone (TSH) (26%), TST (45%), Total T3 (TT3) (32%), TT4 (28%), VitD (19%), VB12 (46%). Overall 29% of QC samples on all tests on all devices had values greater than 2 SDs. g. In February 2015, the data revealed the following tests showed percentage of QC samples with more than 15% of values greater than 2 SD: FT4 (26%), SHBG (87%), TT3 (33%), VitD (24%), VB12 (20%). Overall 24% of QC samples on all tests on all devices had values greater than 2 SDs. h. In March 2015, the data revealed the following tests showed percentage of QC samples with more than 15% of values greater than 2 SD: SHBG (42%), TSH (20%). Overall 20% of QC samples on all tests on all devices had values greater than 2 SDs. i. In April 2015, the data revealed the following tests showed percentage of QC samples with more than 15% of values greater than 2 SD: SHBG (16%), total Prostate Specific Antigen	D5791		

FOIA Confidential Treatment Requested by Theranos TS-0917938

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
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D5791	Continued From page 52 (tPSA) (22%), VB12 (60%). Overall 21% of QC samples on all tests on all devices had values greater than 2 SDs. j. In May 2015, the data revealed the following tests showed percentage of QC samples with more than 15% of values greater than 2 SD: SHBG (34%), tPSA (22%). Overall 26% of QC samples on all tests on all devices had values greater than 2 SDs. k. In June 2015, the data revealed the following tests showed percentage of QC samples with more than 15% of values greater than 2 SD: SHBG (23%). Overall 14% of QC samples on all tests on all devices had values greater than 2 SDs.	D5791		

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EXHIBIT 21

PT/INR PATIENT IMPACT ACCESSMENT

Theranos uses the Siemens BCS-XP instrument for running the PT/INR assay.

In its shipment of reagents to Theranos, Siemens included notification in late March 2015 indicating that stability post-reconstitution for the Dade Innovin reagent used for PT/INR assay was changed from 10 days (closed vial) at 2-8°C to 2 days (closed vial) at 2-8°C. However, the laboratory staff did not appropriately modify their procedures to account for this reduced reagent stability time.

The notification from Siemens indicating reduced stability for the reagents accompanied shipment of reagent lot # 539280. This reagent lot was first used for testing patient samples on 3/23/2015. Theranos does not have the documentation for the MNPT calculation done for lot # 539280 in 3/2015 before it was put in use for patient sample testing.

Theranos reviewed all quality control (QC) data for PT/INR for the time period that this lot of Dade Innovin reagent was in use. The first failed QC was observed on 3/30/2015 and the first patient sample tested following this occurred on 4/3/2015.

In addition, proficiency testing results were reviewed during this time period. The two proficiency testing evaluations performed with CAP for PT/INR reported on 3/2/2015 and 6/19/2105 were 100% acceptable.

On 9/25/2015, the PT/INR assay was discontinued in the Theranos Newark CLIA laboratory, and patient samples received after this date were sent to a third party reference laboratory for testing.

From 4/3/2015 until this issue was discovered and remedial action taken on 9/25/2015, 83 unique patient results from 39 unique patients were tested for PT/INR on the BCS-XP. Out of an abundance of caution, for all 83 patient samples tested during this time period, corrected reports were issued beginning on 11/10/2015 and completed on 11/12/2015. PT/INR results were voided on these corrected reports. A list of the requisitions for which corrected reports were issued can be found here:

159791

160858

161033

162793

163300

164858

165148

165669

165770

166627

178296

178986

179214

180451

180545

181385

181428

182381

182708

183526

184040

184961

185456

185867

186006

186039

186588

187135

189401

189781

190643

191249

191305

191458

191721

192031

193534

194315

194403

196944

197048

197190

198558

202935

204789

206353

207428

209400

210595

210597

210611

211306

211482

213057

215983

217574

219944

220940

221215

222957

225571

226212

227958

228288

228944

229879

230663

231412

232546

233506

234919

235368

236146

242694

242826

244512

251495

253087

254334

255651

256384

256356

256952

EXHIBIT 22

MEMORANDUM OF INTERVIEW

CASE NUMBER	:	2204323-MF
PERSON INTERVIEWED	:	Dr. Kingshuk Das
PLACE OF INTERVIEW	:	Videoconference Call
DATE OF INTERVIEW	:	February 1, 2021
TIME OF INTERVIEW	:	3:35 P.M.

On February 1, 2021, Dr. Kingshuk Das (DAS) was interviewed by videoconference call regarding his knowledge of and employment with Theranos. Assistant United States Attorney Robert Leach, Food and Drug Administration-Office of Criminal Investigation Special Agent George Scavdis, and I participated in the interview. DAS was instructed during the interview that he should not reveal any communications he had with attorneys as they may be protected by attorney/client privilege. The following is a summary of the statements made during the interview.

DAS works remotely for Invitae and currently resides in Minnesota. He worked at UCLA before his employment with Theranos.

DAS first learned about Theranos from a job advertisement. He applied for the position of laboratory director and was interviewed by Elizabeth Holmes (HOLMES), Sunny Balwani (BALWANI), Daniel Young, (YOUNG), and possibly one other person. During the interview, DAS learned the position would be as lab director for Theranos' Newark facility. He was told to anticipate "a few weeks of paperwork," which he later learned was responding to the CMS Form 2567. HOLMES and BALWANI told to DAS CMS had conducted an audit, and that a few irregularities had been identified, but specifics were not discussed. DAS described the interview overall as pleasant, and HOLMES and BALWANI as charismatic. DAS started with Theranos as a contractor in December 2015, and commuted one day per week to the San Francisco Bay Area while continuing to work at UCLA. DAS became a full time Theranos employee in March 2016 and was employed with Theranos until he was laid off in June 2018. DAS worked for Theranos, and was paid a yearly salary by Theranos.

Theranos had a full legal team in place, and DAS interacted with that team often. This was unusual for him.

Theranos' lab as well equipped, and the staff was good but "needed seasoning." Some of the laboratory staff included Gurbir Sidhu, Hoda Alamdar, and Calvin Leung. Theranos' microbiology lab was in operation when DAS started at Theranos, and he believed the Arizona lab was fully operational. Theranos' proprietary testing had been shut down and DAS did not think any Edison or modified devices were operational. Edison devices were never used in the CLIA laboratory during DAS' tenure at Theranos. Some clinical samples were sent to either ARUP or Mayo for processing.

DAS identified Tina Lin as the person most familiar with the Edison data, and YOUNG as having the most knowledge of the Edison device overall. YOUNG, Chinmay Pangarkar

(PANGARKAR), and "Shelia" prepared a high-level PowerPoint document which analyzed Edison test accuracy and precision. This document was presented as part of the CMS audit investigation. DAS received a copy of this document and reviewed it. DAS conducted a Six Sigma analysis of the Edison data and concluded the Edison devices did not perform well, and the accuracy and precision did not meet the level needed for clinical testing. He said that even using a fairly low bar, none of the Edison tests passed an acceptable level. DAS thought YOUNG and PANGARKAR believed the Edison analysis demonstrated the device performed adequately.

DAS' Six Sigma analysis led to an uncomfortable meeting setup by Boies Shiller Flexner (BSF) attorneys with HOLMES, BALWANI, and YOUNG. He believed this meeting took place sometime after the first response to the CMS 2567, but before the second response. DAS presented at this meeting, which took place in the conference rooms where BSF was setup.

DAS said HOLMES was always with the BSF lawyers.

DAS concluded the Edison devices never performed at the level of accuracy and precision required, and could not have generated any results which had clinical value. DAS said there was some push back, but this conclusion was based on Six Sigma metrics. Theranos management suggested this was not a device issue, but rather a quality systems issue. DAS disagreed with that assessment and decided to void all Edison tests. DAS said it was his obligation as the director of record to conduct a patient impact assessment to determine if any harm came from a laboratory error.

PT/INR results were also voided because the assay, which used a BCS-XP device, was run improperly. The calculations associated with the test were done incorrectly, and quality control was poor. DAS said there was no way to salvage any of the test results. DAS believed he documented his work at this information should be contained in the contents of his Theranos computer hard drive. He also communicated these results to counsel, and to Brian Lipszin (LIPSZIN), a contractor who helped craft Theranos' final response to CMS. DAS did not know who hired LIPSZIN.

Theranos did not provide much Edison accuracy or precision data to CMS when responding to the Form 2567, and instead focused on laboratory remediation instead of directly responding to the issues. DAS said it was not his responsibility to consider business implications.

DAS knew Sunil Dhawan, [Adam] Rosendorff, and [Arnold] Gelb were former Theranos laboratory directors. He never spoke to them.

DAS had private meeting with HOLMES he described as general meetings where they would check-in with each other. DAS mentioned his finding to HOLMES, and said these conversations did not go well. HOLMES was not a laboratorian, and he needed to discuss certain topics at her level. He specifically remembered telling HOLMES that approximately one dozen female patients had PSA [prostate-specific antigen] results reported. He said HOLMES seemed perplexed by the issue, and to prove her point, identified an abstract which said females could have PSA in their blood. DAS said that while it was in the realm of possibility that a woman could have PSA in her blood, it was unlikely that twelve women had a reportable result.

There was an effort to rebuild the Theranos CLIA lab by bringing up one test at a time. DAS believed the first test they worked on was the CBC [complete blood count] run on an Advia 2120

with blood drawn by venipuncture. DAS did not think this process concluded due to the settlement with CMS.

After the CLIA lab closed, DAS continued his internal investigations until those were shut down by Theranos' general counsel in late 2017 or early 2018. DAS said addressing the deficiencies identified in the CMS 2567 was just the "tip of the iceberg," and his investigations continued to "follow the thread" into other areas. DAS believed he finished his investigation of Theranos' proprietary testing by the time he was shut down. DAS provided periodic updates to David Taylor, and WilmerHale attorneys Mugmon and Davies.

During his last six months, DAS worked on a non-clinical Zika assay that was going to be submitted to the U.S. Food and Drug Administration (FDA).

DAS did not work on the minilab device, but saw some data that was going to be used for HOLMES' AACC [American Association for Clinical Chemistry] presentation. He and Phoenix lab director Don Tschirhart (TSCHIRHART) were initially going to attend the AACC conference and participate in a roundtable discussion, but were politely uninvited by Daniel Edlin. DAS was told they were not needed and their spots would be used for someone else.

DAS believed he only had two direct interactions with BALWANI before he left Theranos because his mother fell ill. DAS heard gossip about BALWANI's role in the company similar to what was published in John Carreyrou's (CARREYROU) book and in other new articles.

DAS has not been deposed in relation to any Theranos litigation. He provided Zika information on the condition of anonymity to CARREYROU for an upcoming podcast. He did not speak with any other journalists.

DAS reviewed document THER-0534700 to THER-0534792 and said that he drafted, reviewed, and signed the document. Most of the content, however, was the work of Theranos attorneys. He did not know what role HOLMES played in drafting this document, but would have been surprised if she had not reviewed it. Most of his CMS interactions were with local inspector Gary Yamamoto
(YAMAMOTO) with whom he exchanged periodic emails regarding sending data. DAS, HOLMES, TSCHIRHART, and Heather King attended a meeting in Washington, D.C. at CMS with Karen Fuller's supervisor. YAMAMOTO and Sarah Bennett attended by telephone.

DAS' Edison review data was stored on Theranos' share drives and labelled with D-tag numbers corresponding to the CMS 2567. There were also LIS [laboratory information system] data dumps on his computer.

The interview ended at 4:35 P.M.

Christopher McCollow

Christopher McCollow — February 15, 2021

U.S. Postal Inspector — Date

Attachments:

- THER-0534700 to THER-0534792

EXHIBIT 23

MEMORANDUM TO FILE

CASE NUMBER	:	2204323-MF
DATE	:	February 3, 2021
SUBJECT	:	Supplement to Dr. Kingshuk Das Interview

On February 1, 2021, at approximately 5:00 P.M., Dr. Kingshuk Das (DAS) contacted me by telephone and provided additional information relevant to his interview. DAS said Brian Lipszin (LIPSZIN) was someone with significant experience responding to the FDA. He was retained to help work on what DAS called the "lab director's" response to the CMS 2567, instead of the "legal" CMS 2567 response.

On February 2, 2021, DAS sent me an email containing additional information. That information is summarized below:

- DAS, Elizabeth Holmes, Don Tschirhart, and Heather King met with Kate Goodrich at CMS' offices in Washington, D.C. Additional CMS employees were present either in-person or by telephone, including Gary Yamamoto, Sarah Bennett, and Karen Fuller.
- DAS believed HOLMES must have known about Theranos' response to CMS because the responses at the time were largely driven by counsel. HOLMES acknowledged this, "lament[ed] the legal nature of the previous response(s)," and allowed DAS and other laboratory leadership to draft their response without direct involvement of counsel. When counsel became involved and halted further investigation, DAS and his team had analyzed most data from the proprietary methods, including Edison devices and modified Siemens Advia protocols.
- DAS identified the following individuals as laboratory staff: Ashruti Gupta, Angelo Luciano, Lisa Bojorquez, Huy Quach, Amber Venzon, Janki Patel, Brian Martin, Jennifer Trick, and Nafiseh [Last Name Unknown].
- DAS had previously reviewed HOLMES' draft AACC presentation and raised concerns about statements of minilab accuracy versus the standard-of-care which he said were misleading. After some discussion, these concerns and statements were addressed.

On February 3, 2021, DAS sent me an email containing additional information relevant to his interview. That information is summarized below:

- DAS identified the third scientist who prepared the Edison data as Sharada Sivaraman. The data, in Excel format, would have been kept on his Theranos laptop.

Christopher McCollow

Christopher McCollow — February 15, 2021

U.S. Postal Inspector — Date

Attachments:

- February 2, 2021 email with Subject – "[EXTERNAL] Re: Interview of Dr. Das"
- February 3, 2021 email with Subject – "[EXTERNAL] Re: Interview of Dr. Das"

EXHIBIT 24

theranos	**Standard Operating Procedure**	Document Number: CL UG-08009 Revision: A
	CLIA Lab	Effective Date: 10/20/2015
LIS App User Guide		

	Name	Title	Signature	Date
Author:	Anam Khan	Case Manager		
Reviewer:	Max Fosque	Sr. Product Manager		
Reviewer:	Gurbir Sidhu	General Lab Supervisor		
Approver:	Sunil Dhawan, MD.	Lab Director		

LIS App User Guide

10/15/2015

Table of Contents

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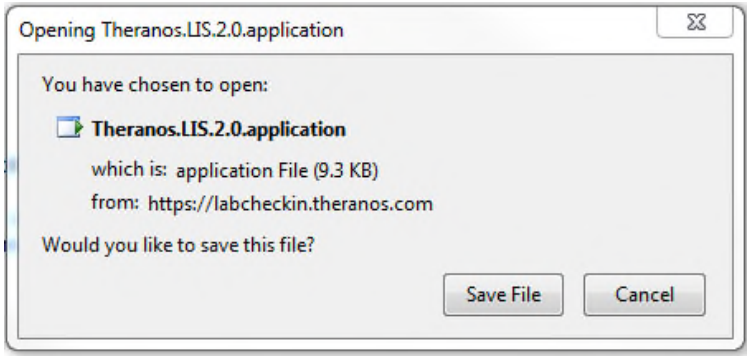
Getting Started

- To install the Theranos.LIS App, open this link in your web browser:

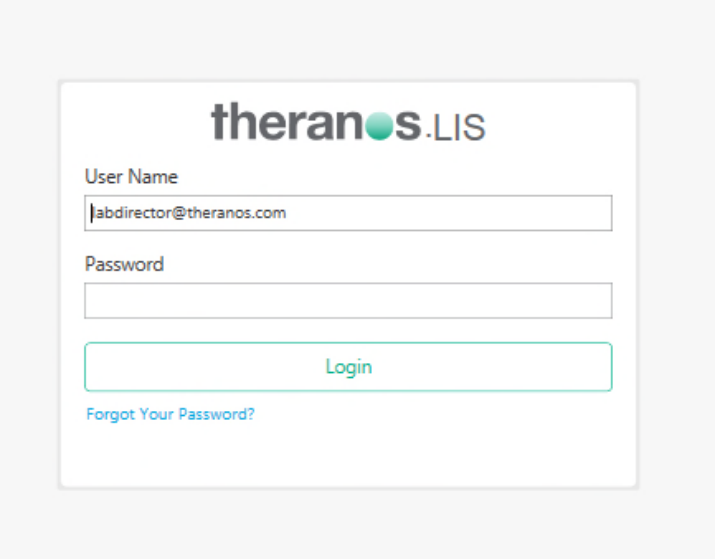
https://labcheckin.theranos.com/LIS2.0.App/publish.htm

- Install any necessary prerequisites and click “Launch” to download the application.



- Click "**Save File**".
- Open the saved file and run the installer.

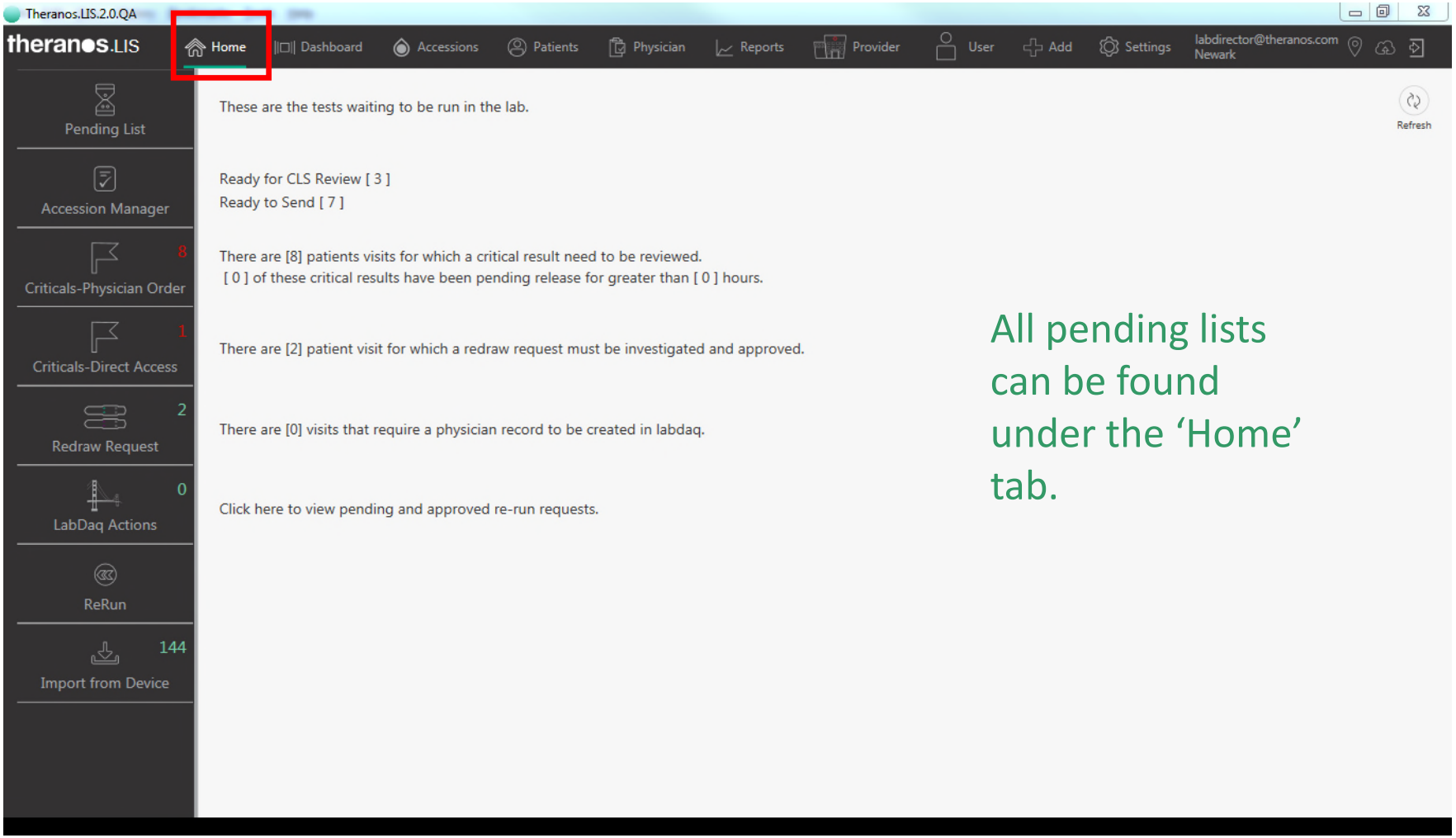
*For any troubleshooting issues, please email/call Helpdesk at Helpdesk@theranos.com (ext. 333)



To log in: Enter your assigned LIS username and password, then click "**Login**".

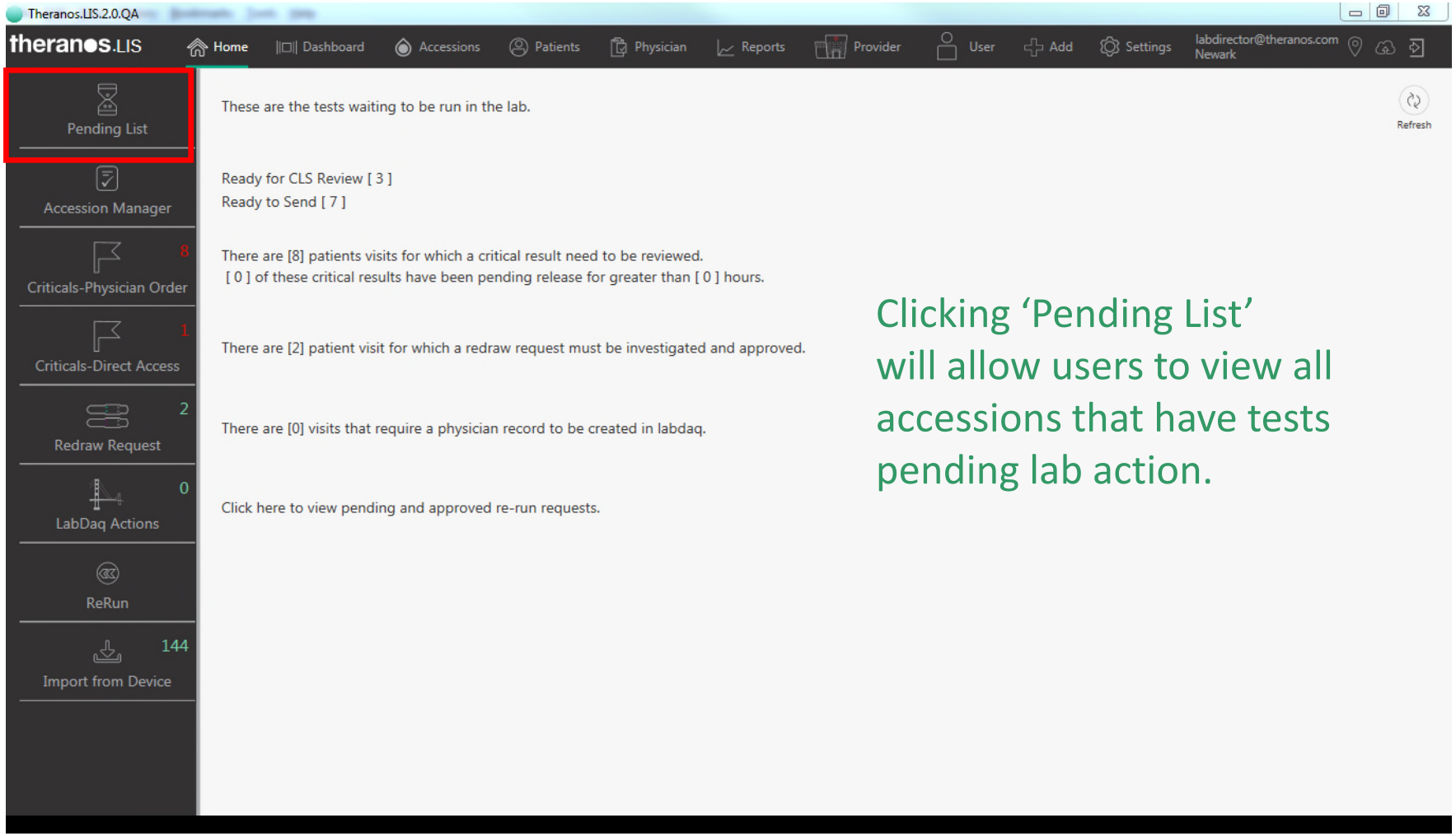
Home & Dashboard

Home



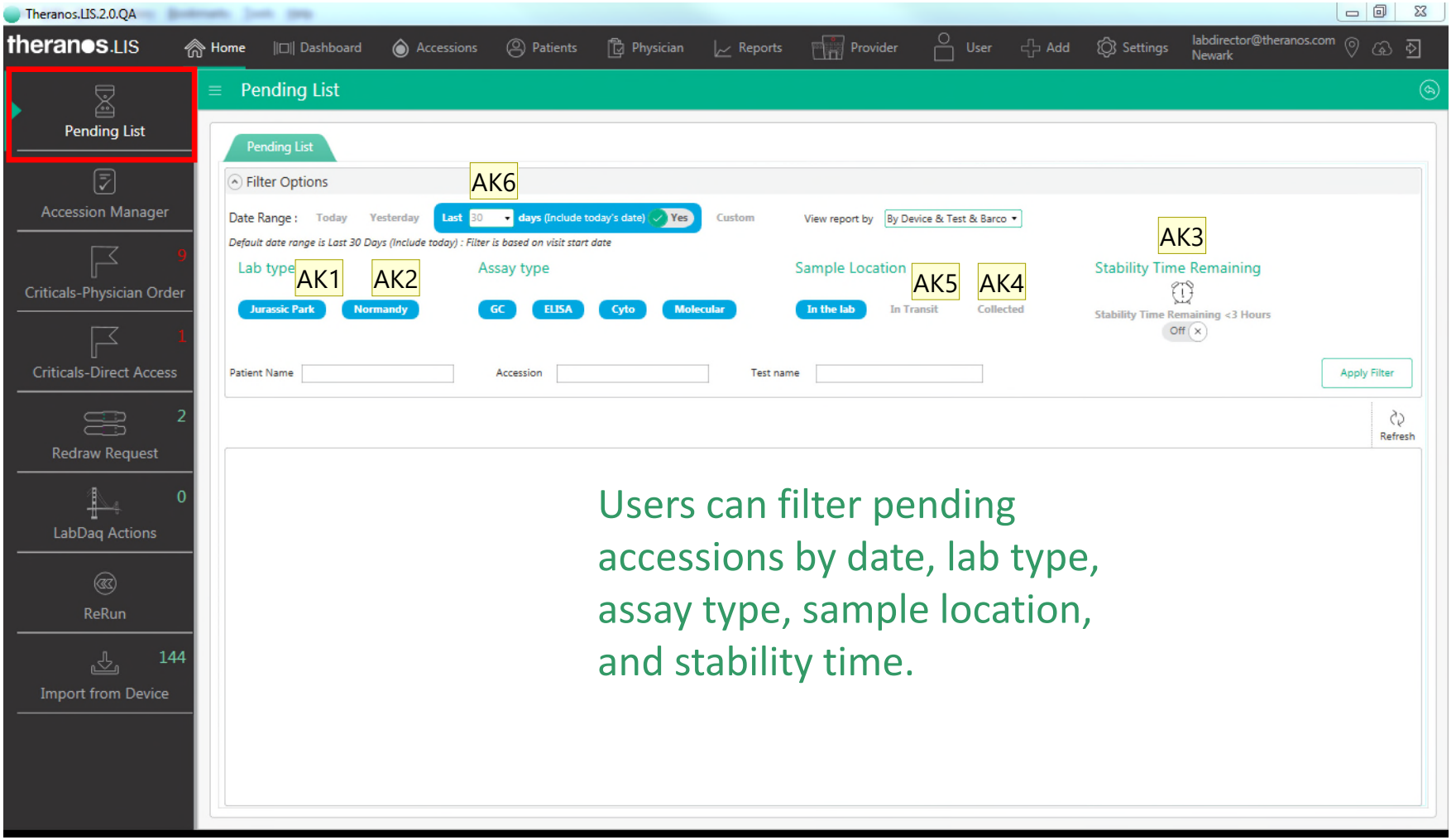
All pending lists can be found under the 'Home' tab.

Home- Pending List



Clicking 'Pending List' will allow users to view all accessions that have tests pending lab action.

Home- Pending List



Slide 11

AK1 Venous samples
Anam Khan, 6/24/2015

AK2 CTNs
Anam Khan, 6/24/2015

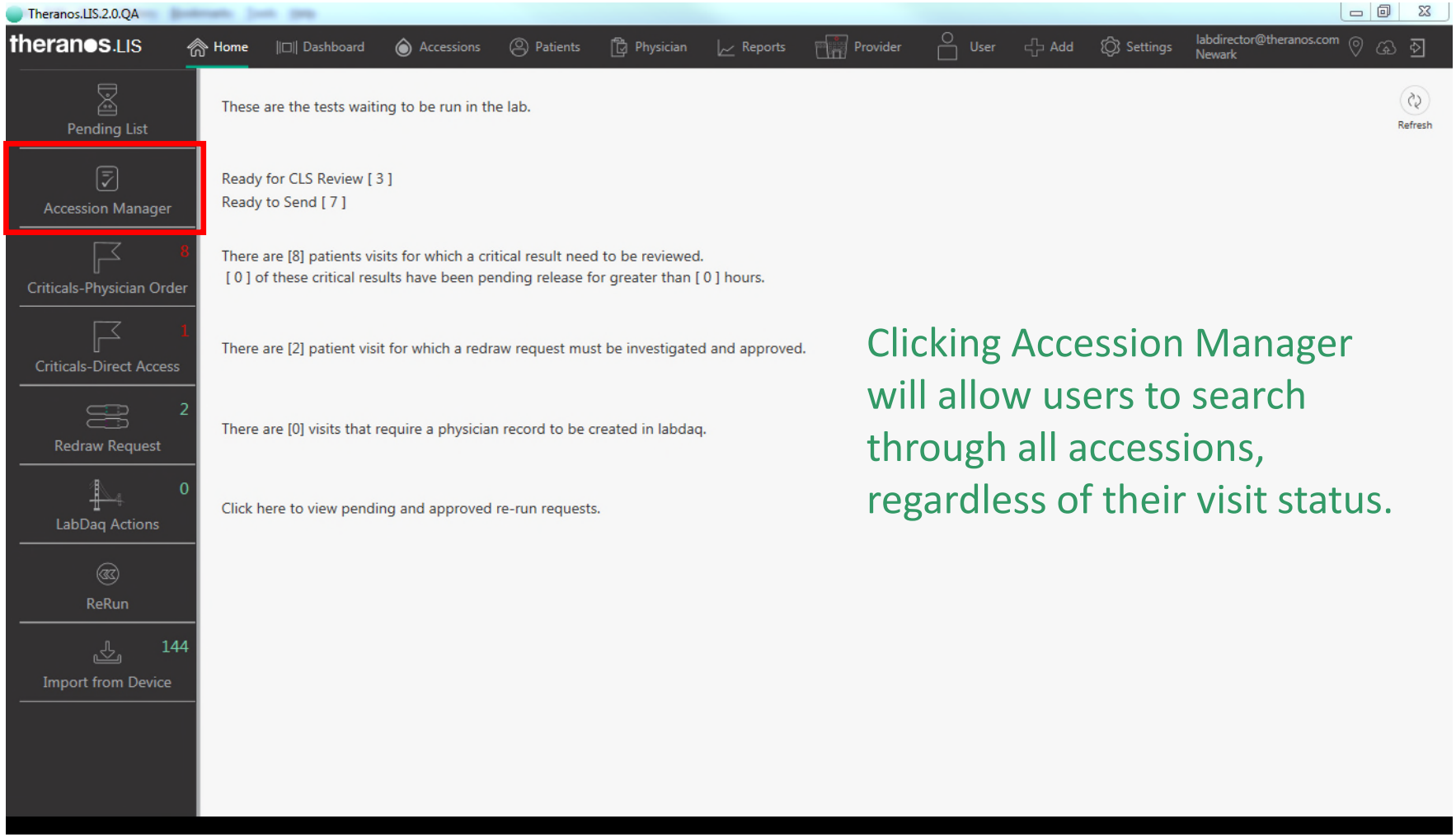
AK3 The # of hours/days a sample is stable in regards to a specific assay
Anam Khan, 6/24/2015

AK4 Still at PSC
Anam Khan, 6/24/2015

AK5 Picked up by the couriers
Anam Khan, 6/24/2015

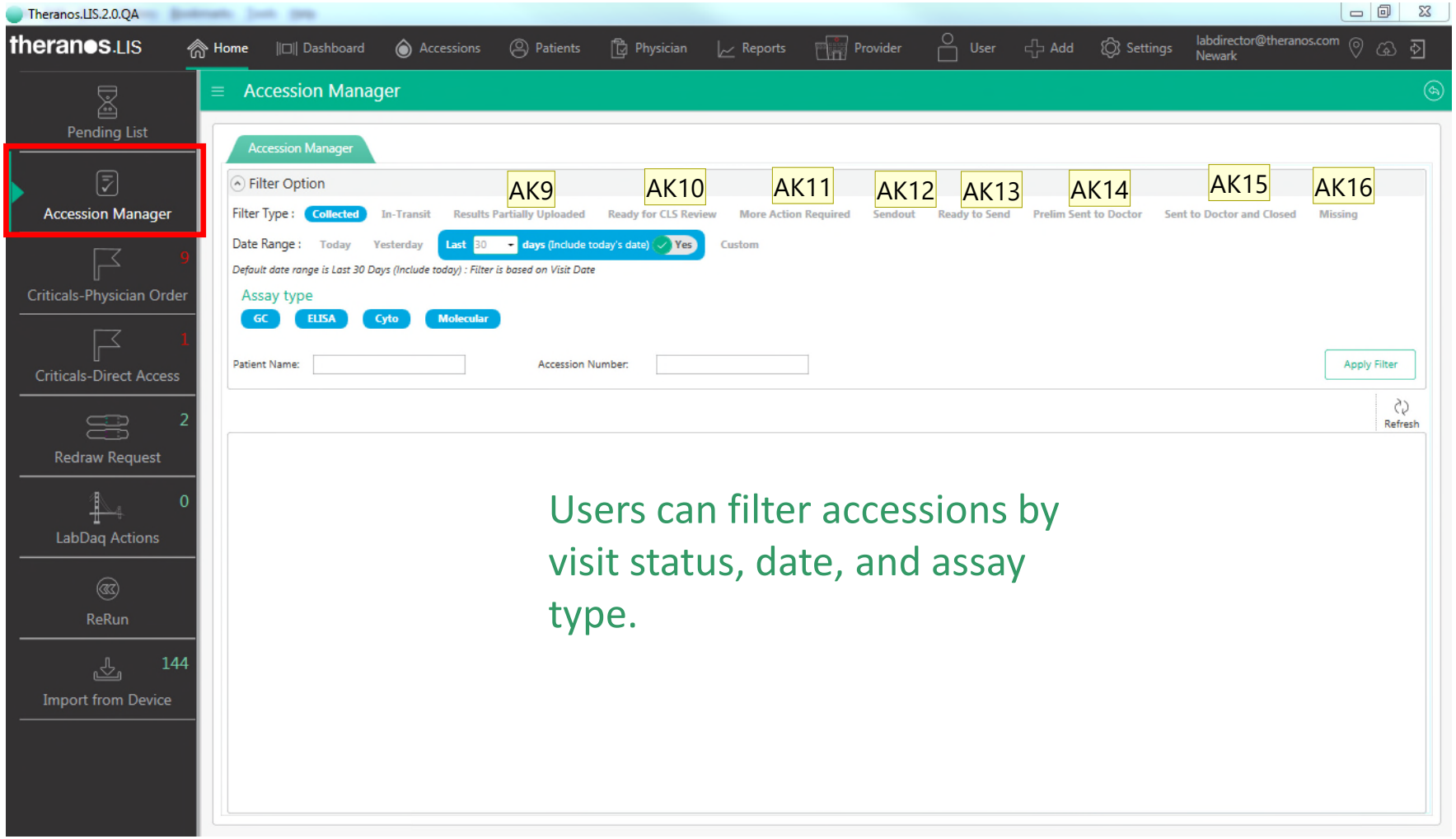
AK6 default is 30 days
Anam Khan, 6/24/2015

Home- Accession Manager



Clicking Accession Manager will allow users to search through all accessions, regardless of their visit status.

Home- Accession Manager



Slide 13

AK9 not all results have been uploaded
Anam Khan, 6/24/2015

AK10 all results uploaded, status= "under lab review", CLS action required
Anam Khan, 6/24/2015

AK11 slide review, manual report, etc.
Anam Khan, 6/24/2015

AK12 sent to ARUP
Anam Khan, 6/24/2015

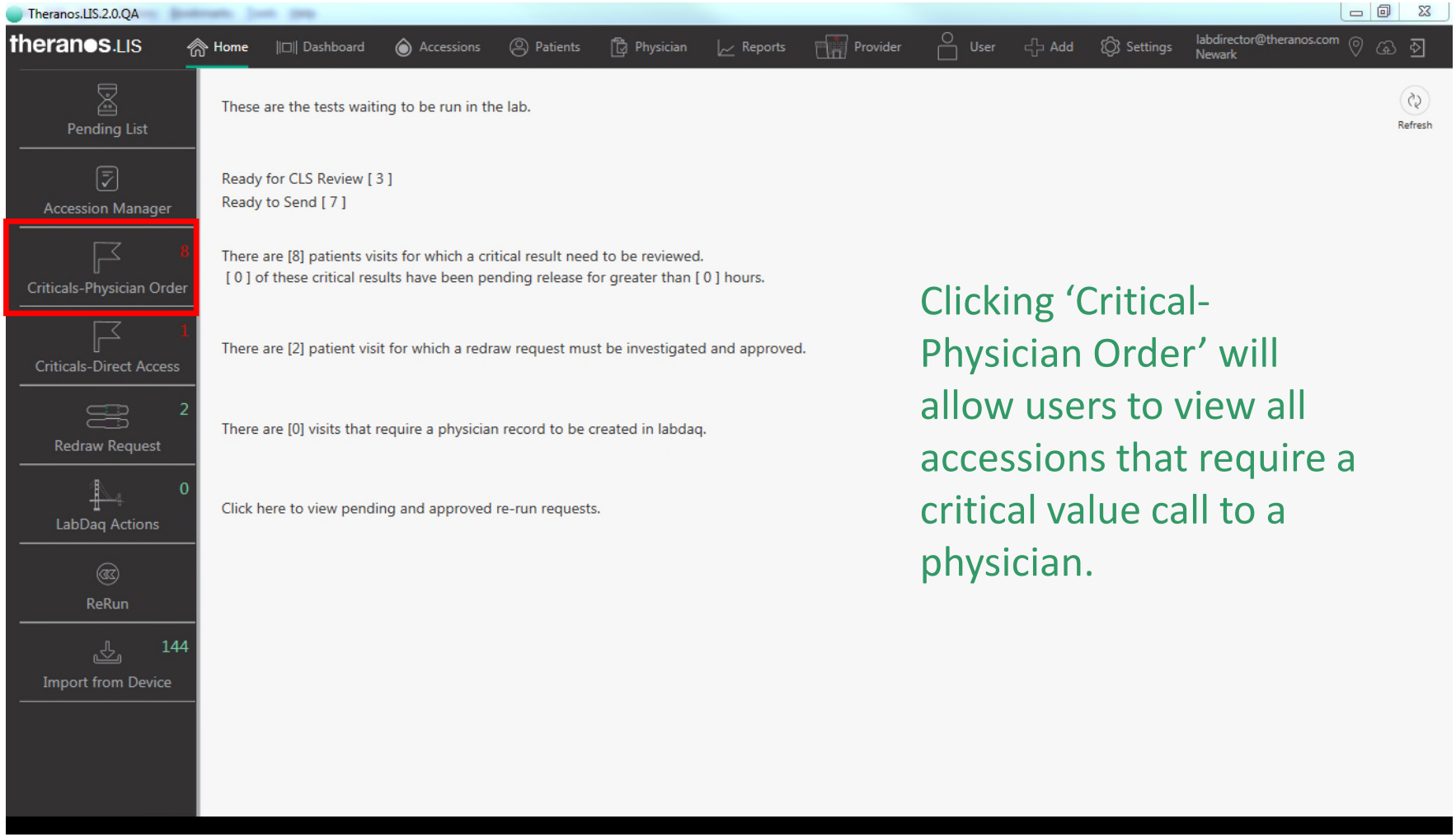
AK13 all results are set to 'doctor-only', CS action required
Anam Khan, 6/24/2015

AK14 Partial results have been sent to physician
Anam Khan, 6/24/2015

AK15 completed visits
Anam Khan, 6/24/2015

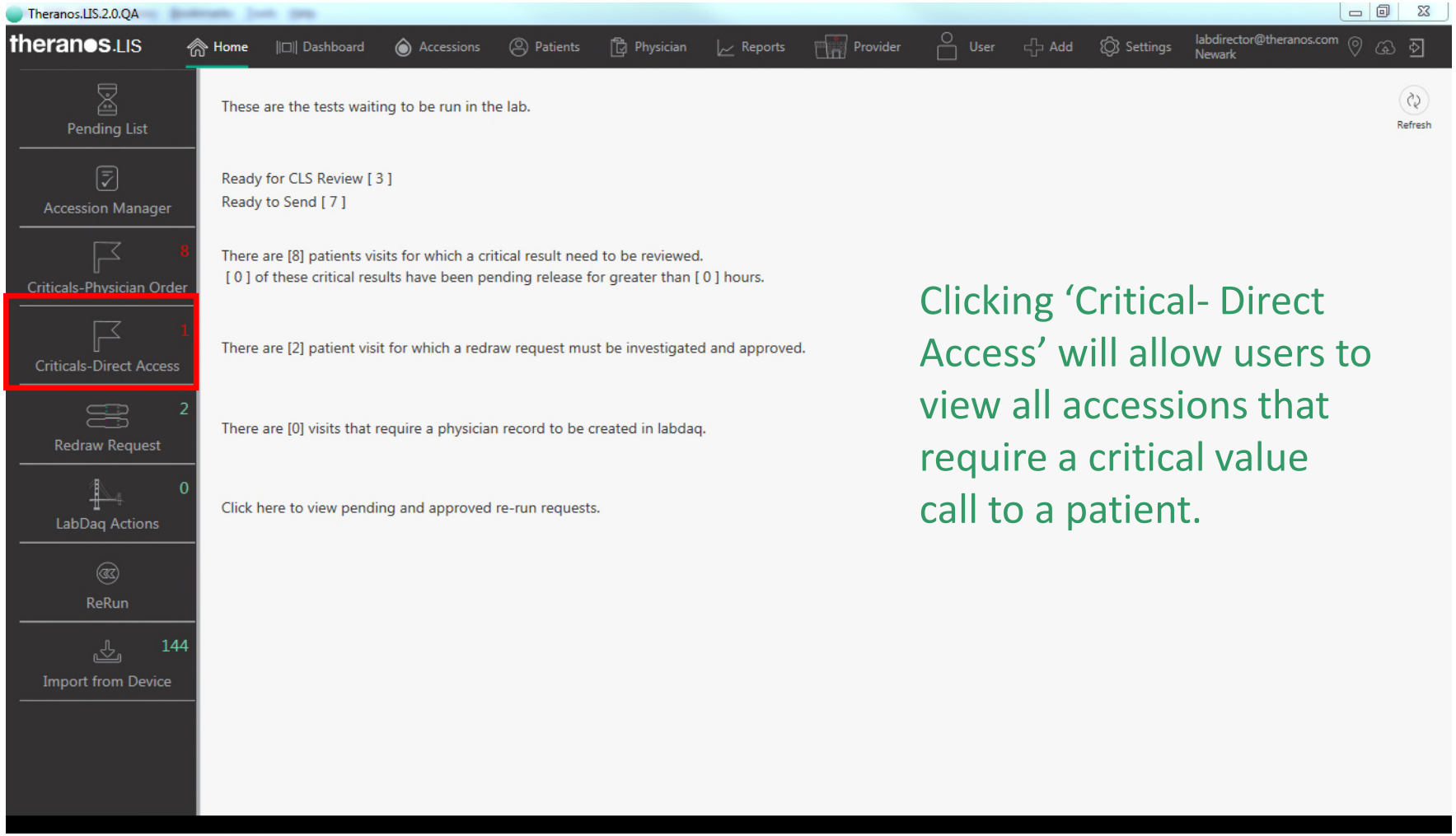
AK16 samples collected, but wasn't received by the lab
Anam Khan, 6/24/2015

Home- Criticals- Physician Order



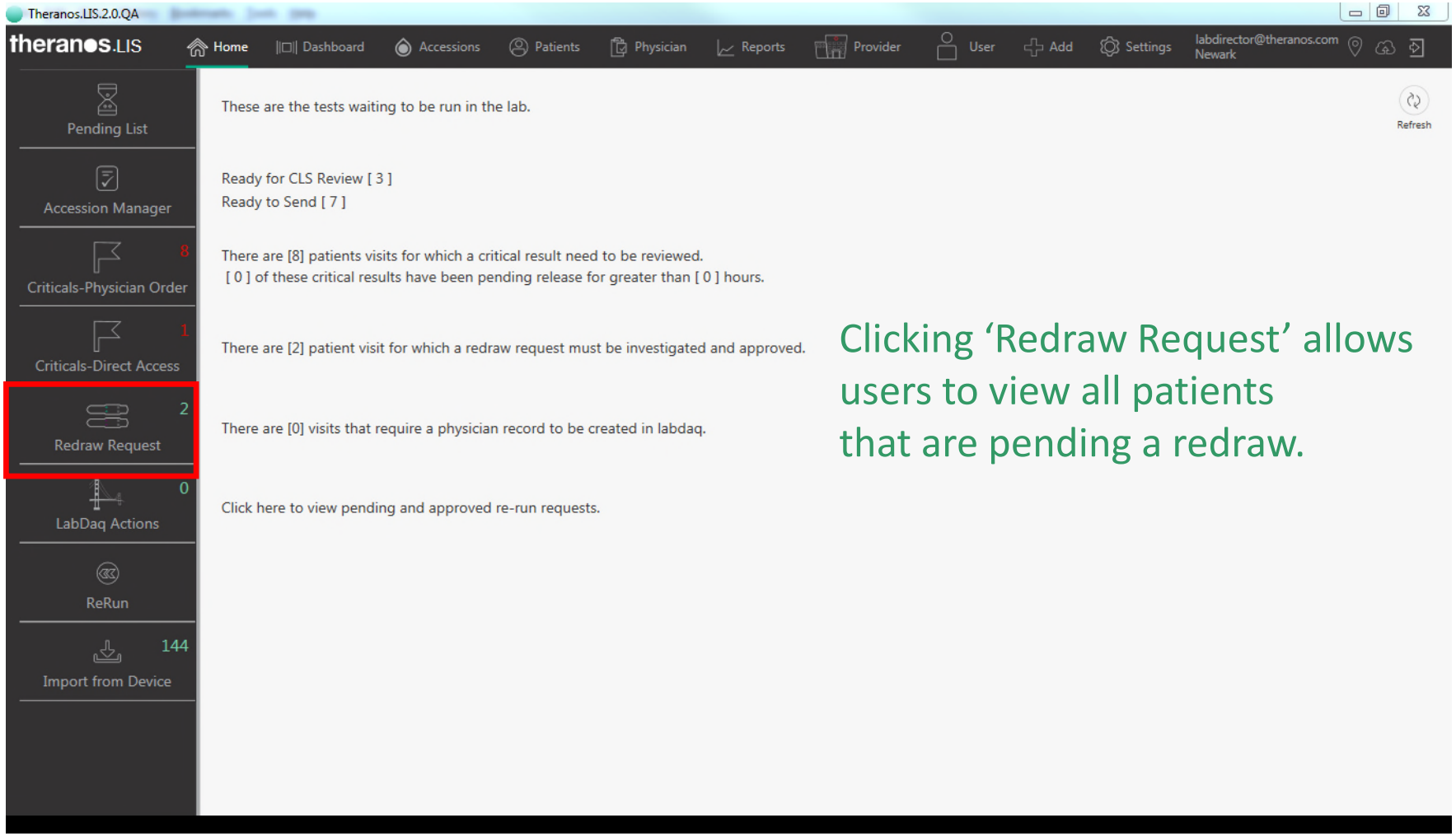
Clicking 'Critical-Physician Order' will allow users to view all accessions that require a critical value call to a physician.

Home- Criticals- Direct Access



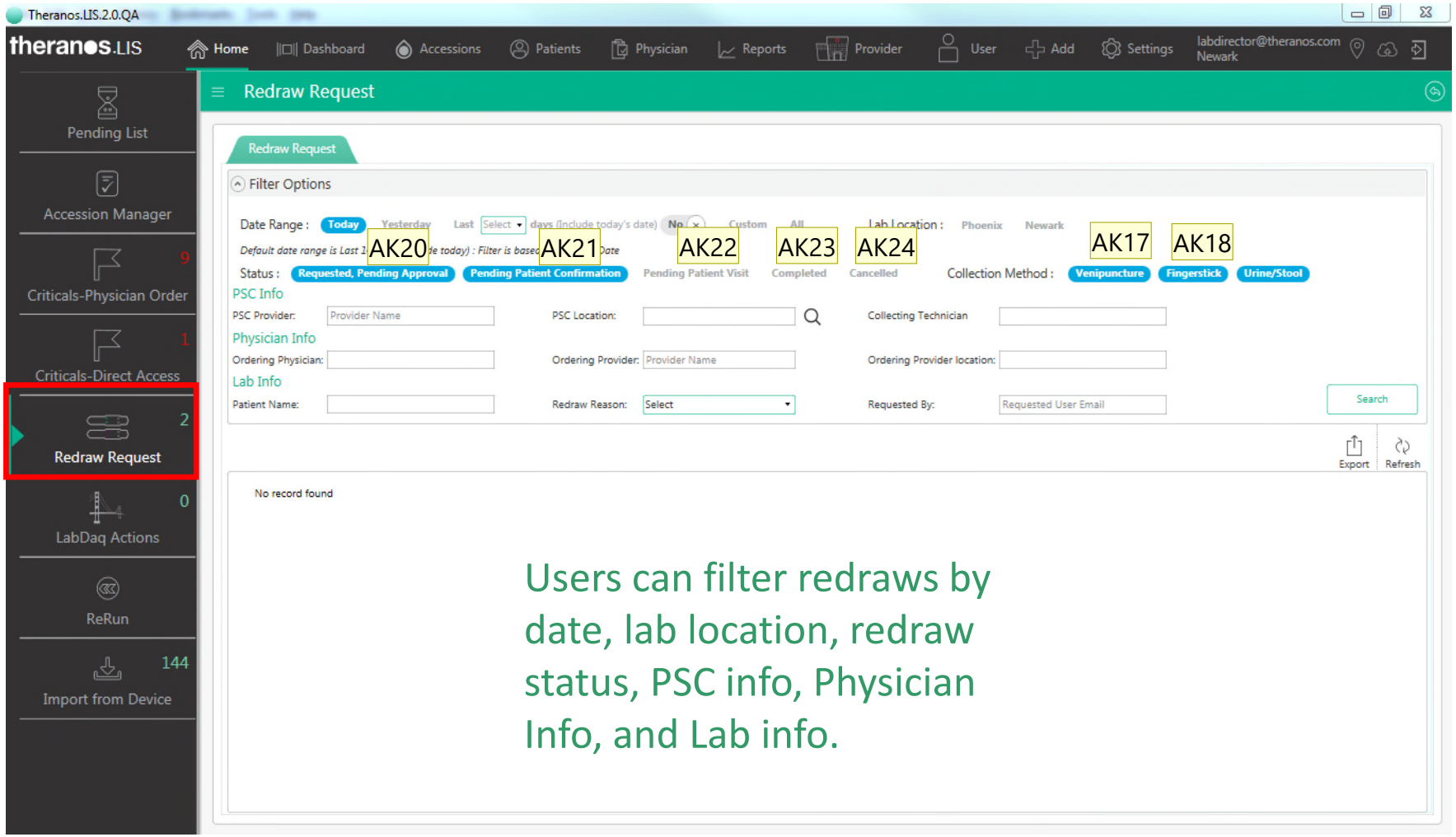
Clicking ‘Critical- Direct Access’ will allow users to view all accessions that require a critical value call to a patient.

Home- Redraw Requests



Clicking ‘Redraw Request’ allows users to view all patients that are pending a redraw.

Home- Redraw Requests



Users can filter redraws by date, lab location, redraw status, PSC info, Physician Info, and Lab info.

Slide 17

AK17 Venous tubes
Anam Khan, 6/24/2015

AK18 CTNs
Anam Khan, 6/24/2015

AK20 redraw requested by CLS, pending approval by lab director
Anam Khan, 6/24/2015

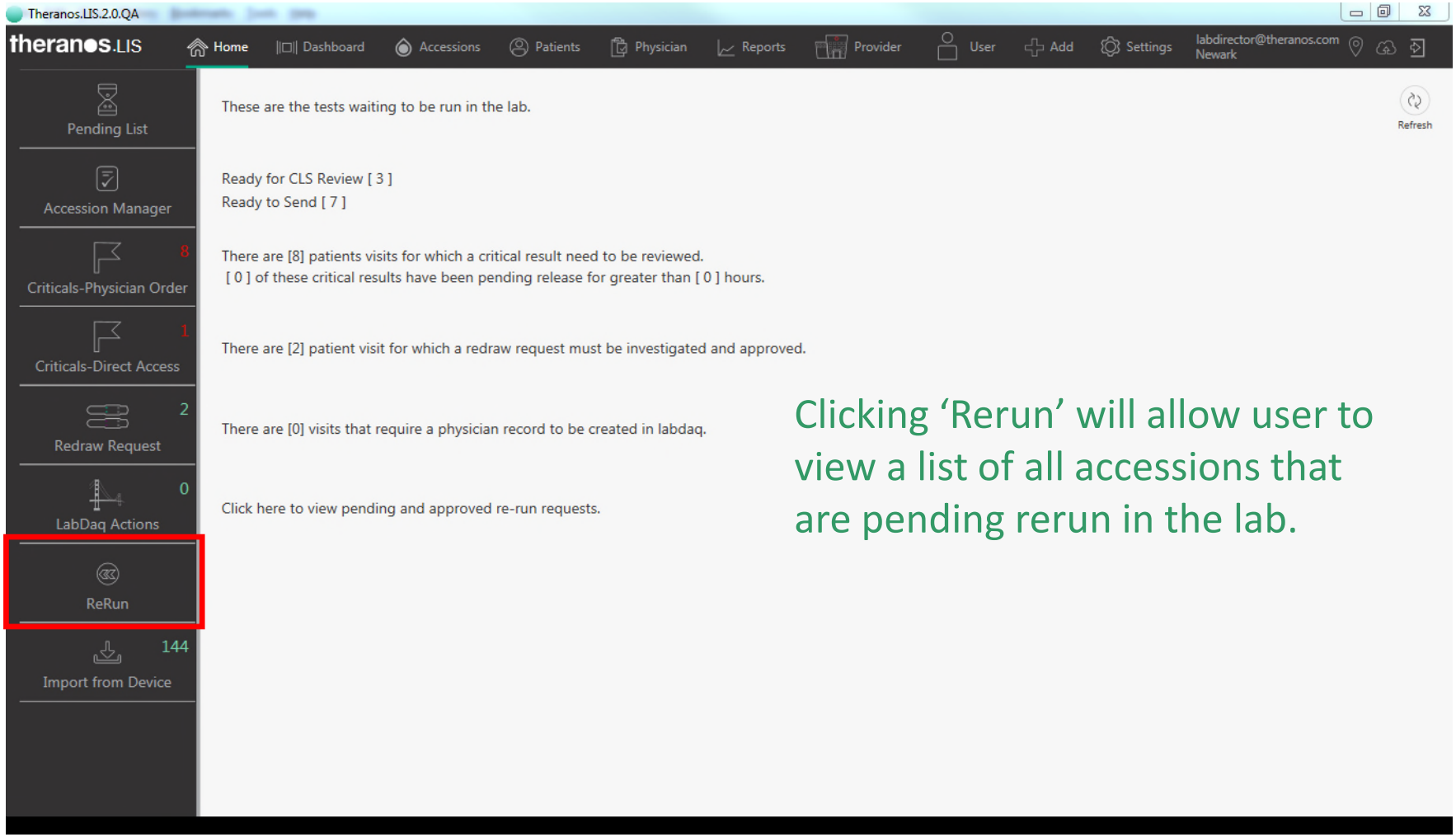
AK21 Redraw approved, pending call to patient and physician
Anam Khan, 6/24/2015

AK22 patient/physician informed, pending patient return
Anam Khan, 6/24/2015

AK23 redraw order used at PSC
Anam Khan, 6/24/2015

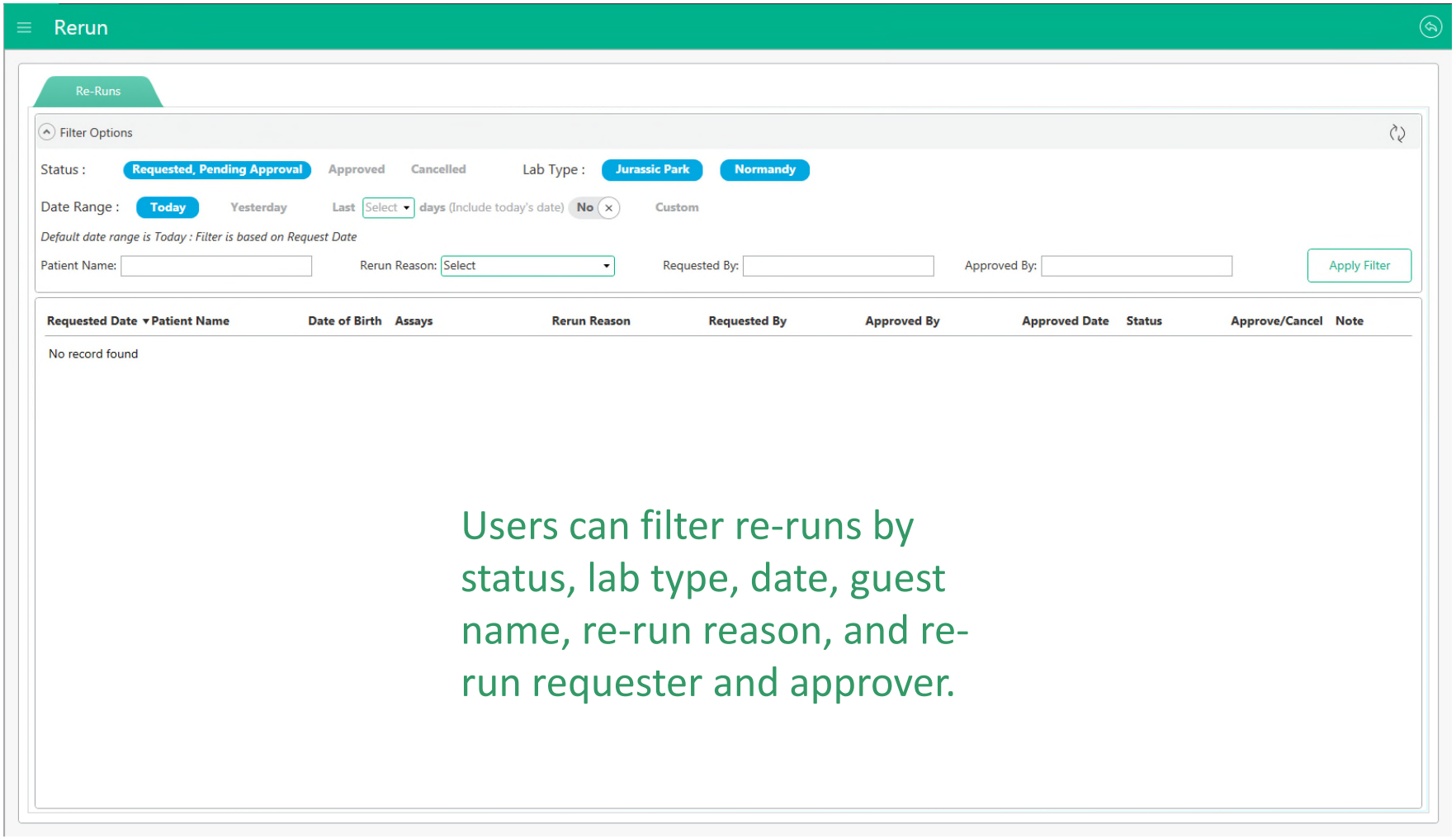
AK24 Canceled at request of lab or patient/physician
Anam Khan, 6/24/2015

Home- Reruns



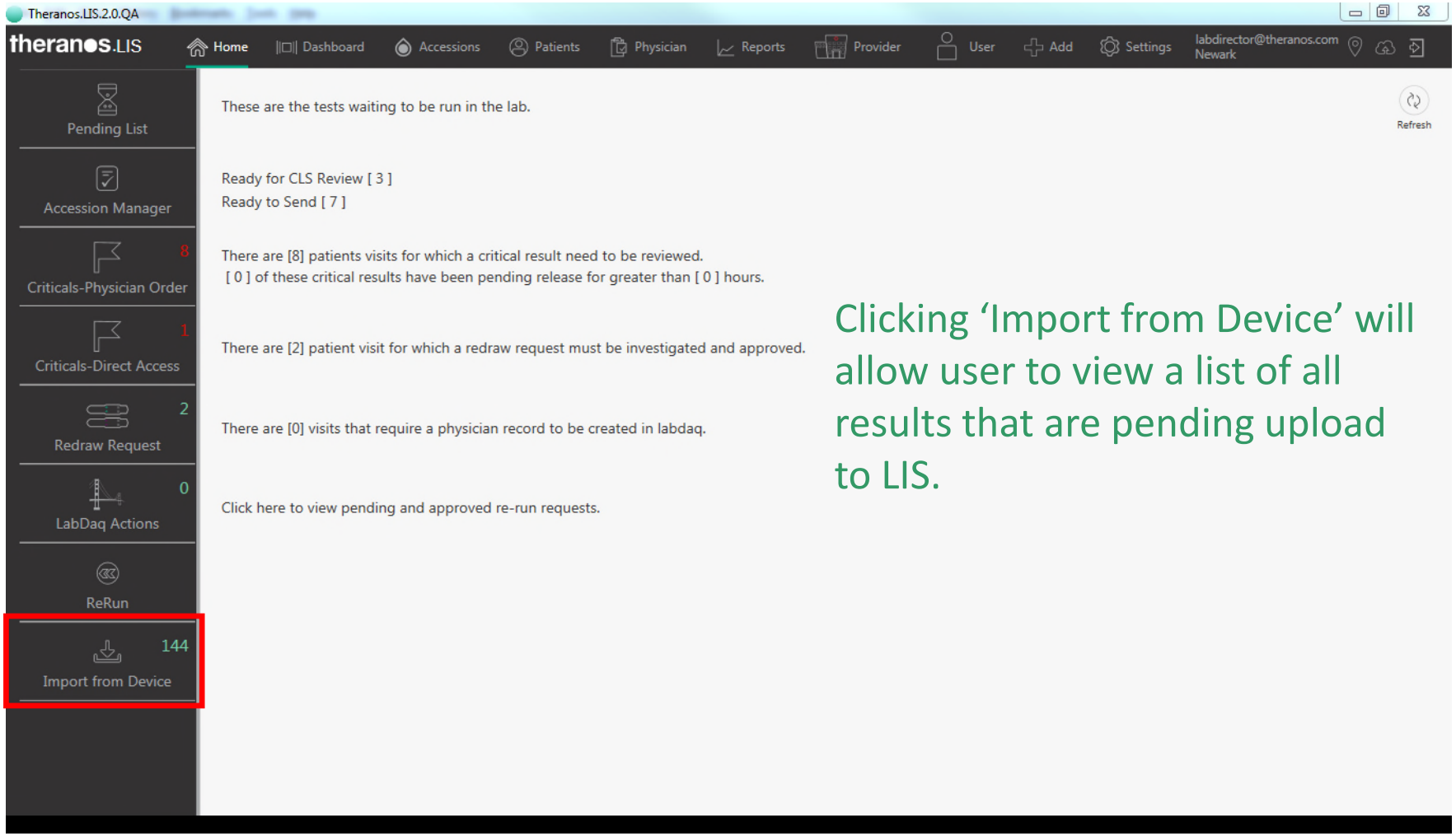
Clicking ‘Rerun’ will allow user to view a list of all accessions that are pending rerun in the lab.

Home- Reruns



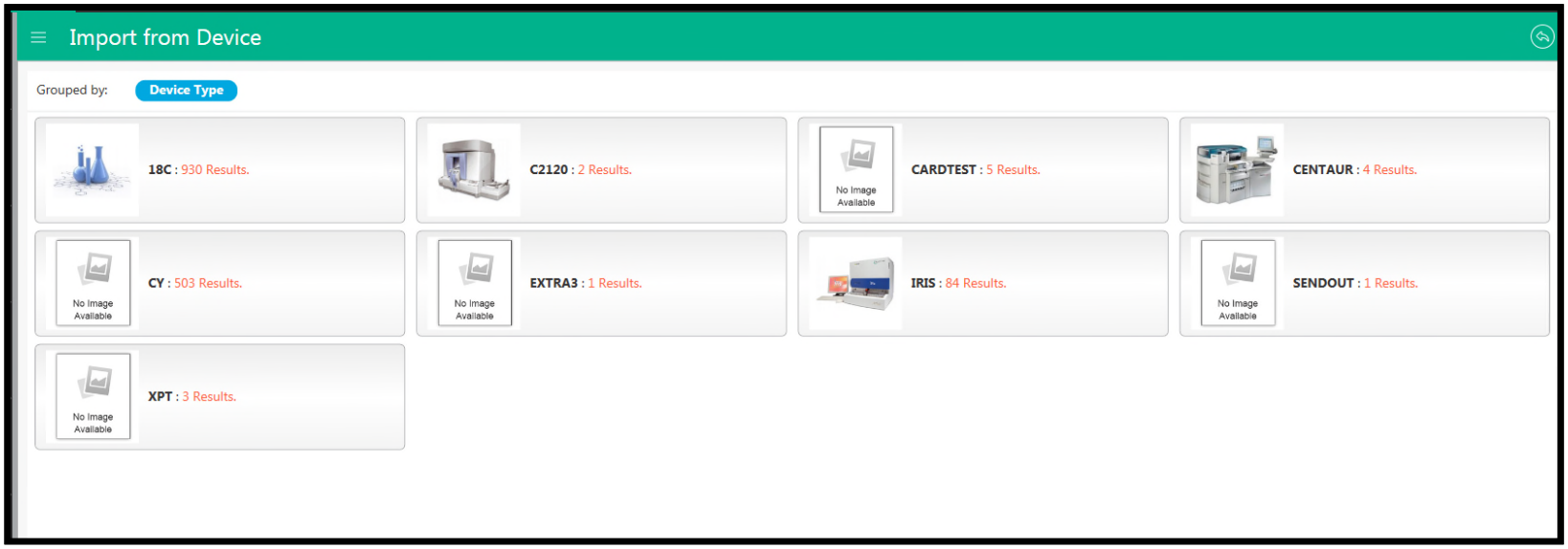
Users can filter re-runs by status, lab type, date, guest name, re-run reason, and re-run requester and approver.

Home- Import from Device



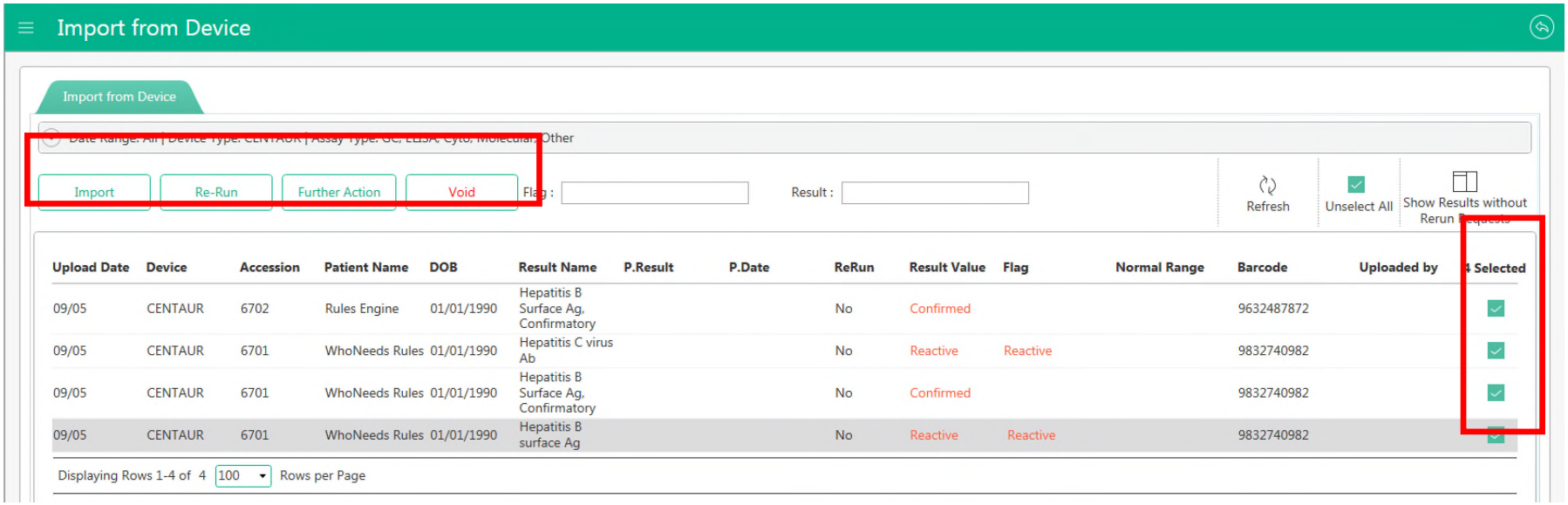
Clicking 'Import from Device' will allow user to view a list of all results that are pending upload to LIS.

Home- Import from Device



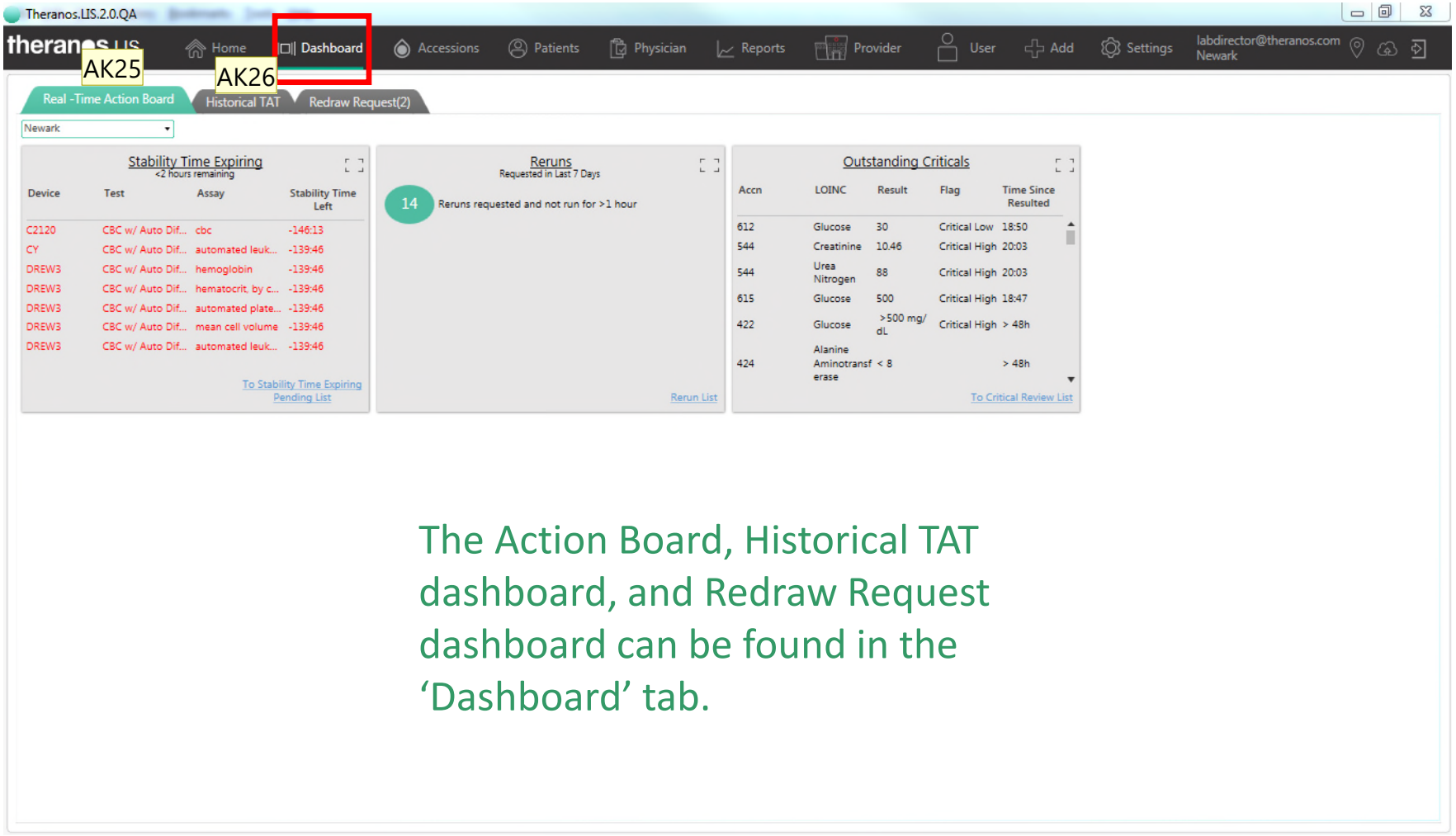
User will first be prompted to select a Device Type.

Home- Import from Device



1. Select a specific patient/accession
2. Perform an action:
   - Import- Changes status of result to ‘under lab review’
   - Re-Run- Create a re-run request for the assay
   - Further Action- Similar to More Action (slide # 43)- gives user option to create an action on the assay (Slide Review, Review Image, Verify Results, Panel Hold, Visit Hold, Result Hold)
   - Void Result- Voids results

Dashboard



The Action Board, Historical TAT dashboard, and Redraw Request dashboard can be found in the 'Dashboard' tab.

Slide 23

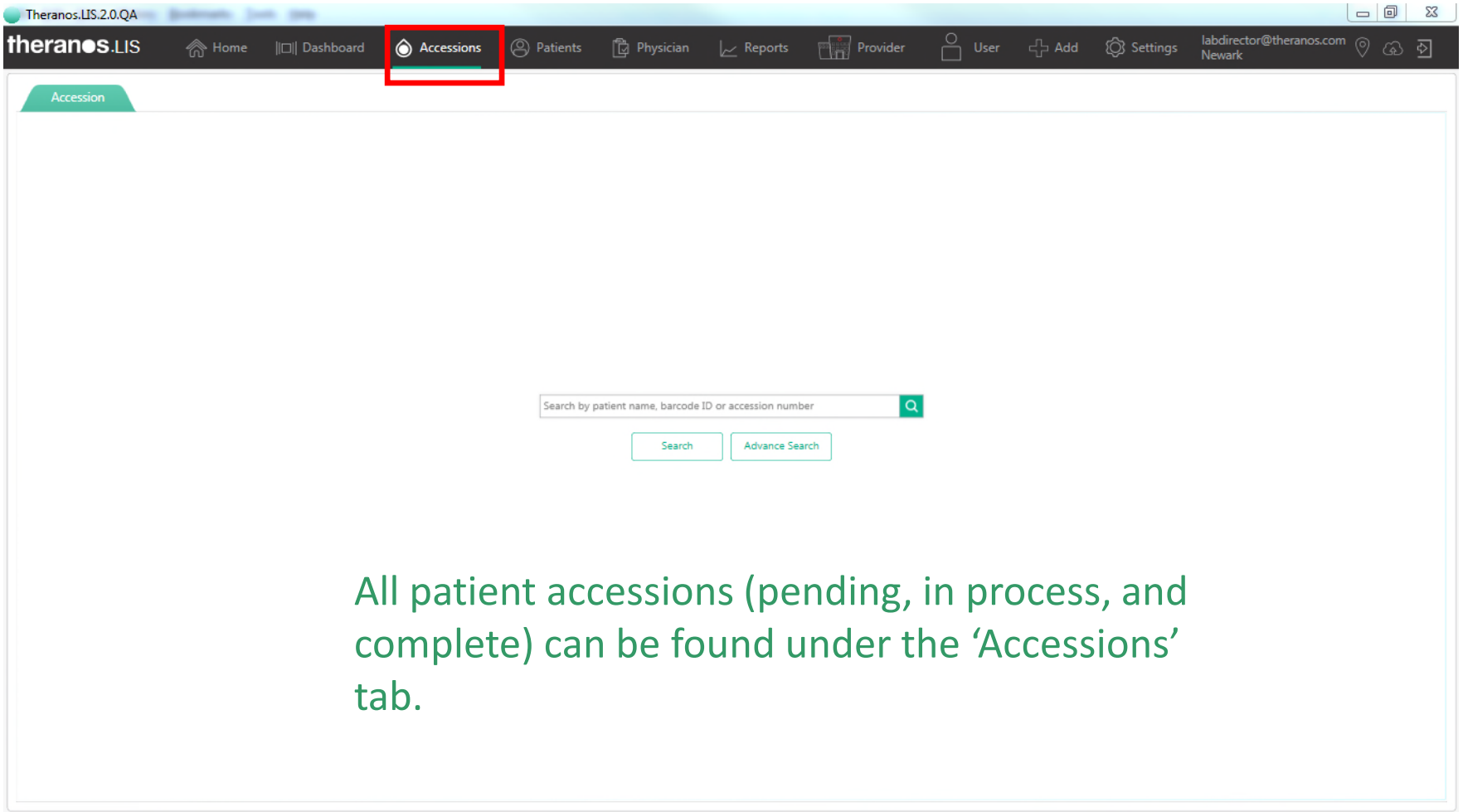
AK25 ?
Anam Khan, 6/24/2015

AK26 TAT- turn around time..time from when patient is drawn to when results are released to physician
Anam Khan, 6/24/2015

Accessions Tab

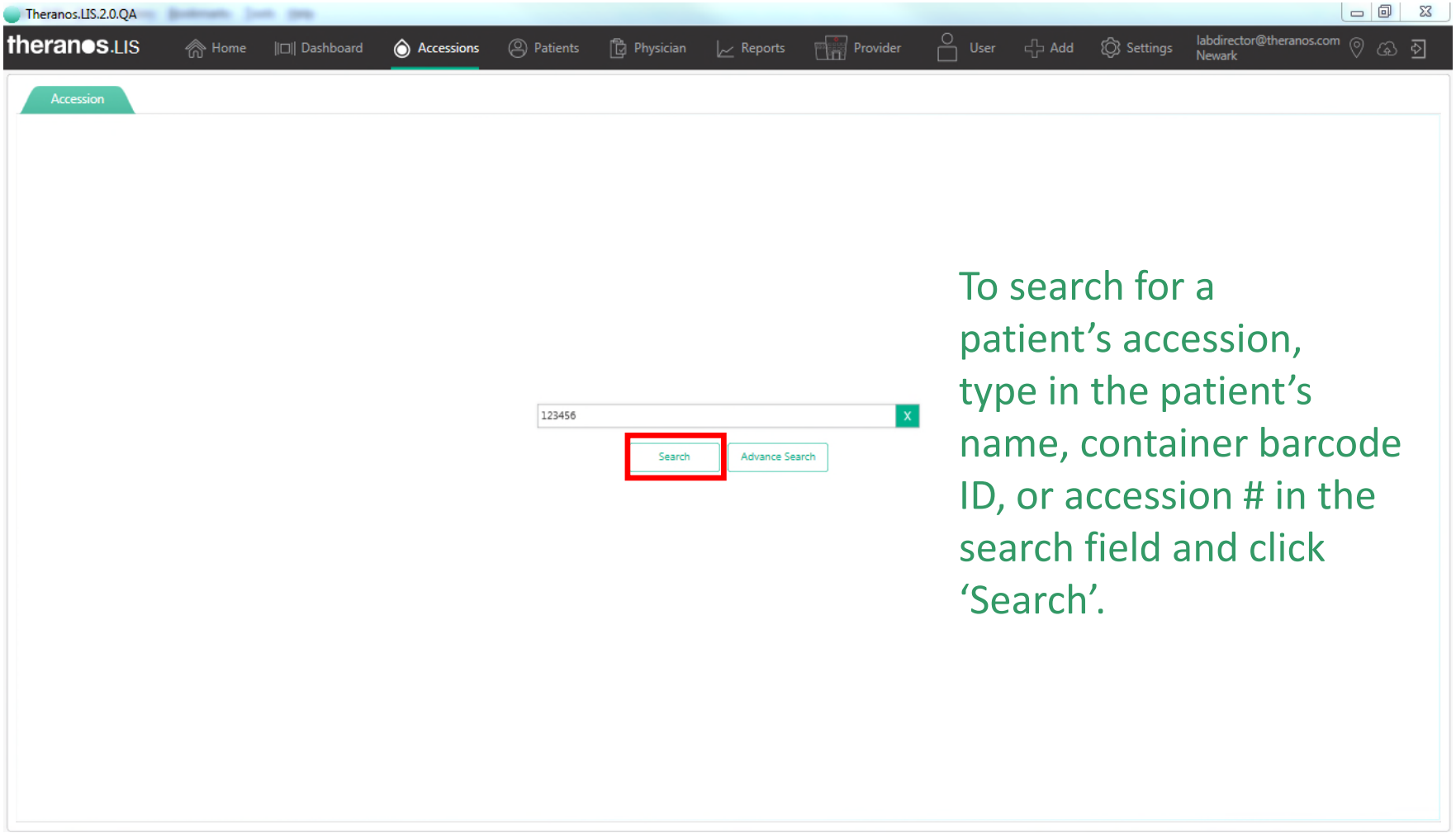
Searching Accessions

Searching for Accessions



All patient accessions (pending, in process, and complete) can be found under the 'Accessions' tab.

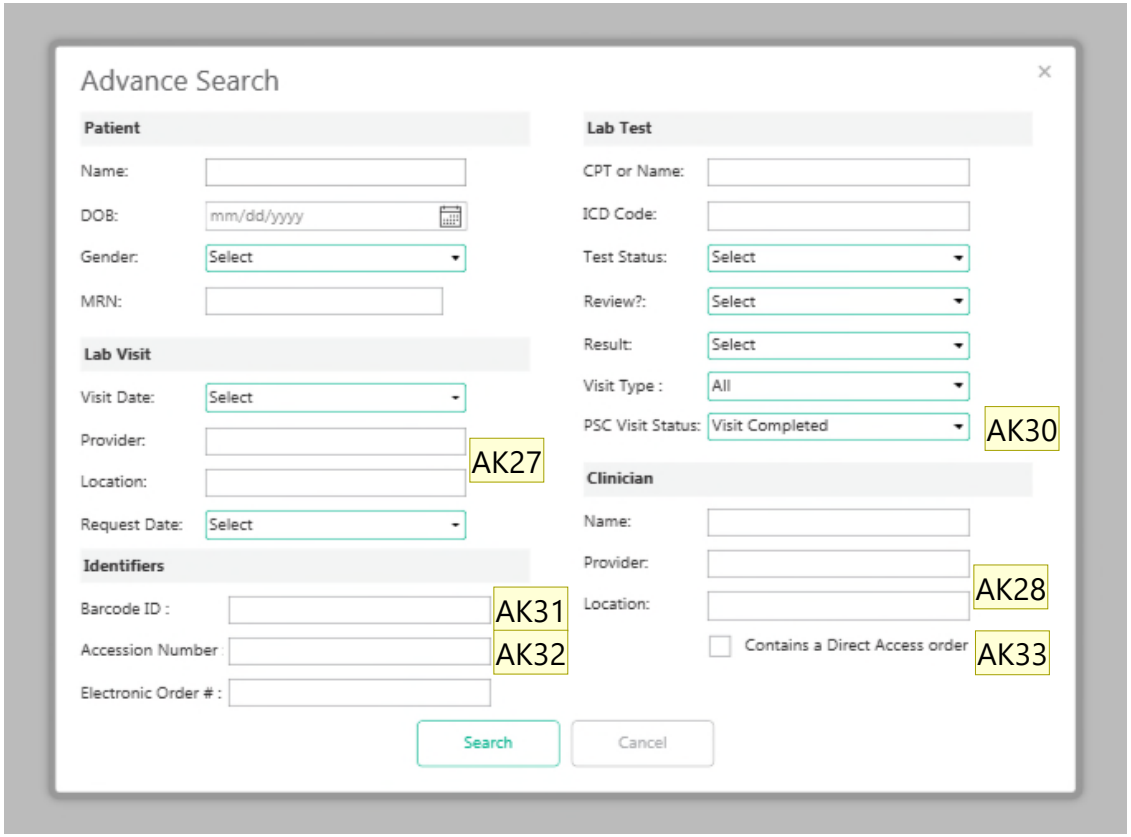
Searching for Accessions



To search for a patient's accession, type in the patient's name, container barcode ID, or accession # in the search field and click 'Search'.

Searching for Accessions

Clicking 'Advanced Search' allows the user to search for accessions with specific parameters.



Slide 28

AK27 Theranos location where the patient is drawn
Anam Khan, 6/24/2015

AK28 The physcian's practice
Anam Khan, 6/24/2015

AK30 Visit not started= order is pending
Visit in process= Patient at PSC
Visit Completed= Visit completed at PSC
Visit Canceled= Visit canceled at PSC
Anam Khan, 6/24/2015

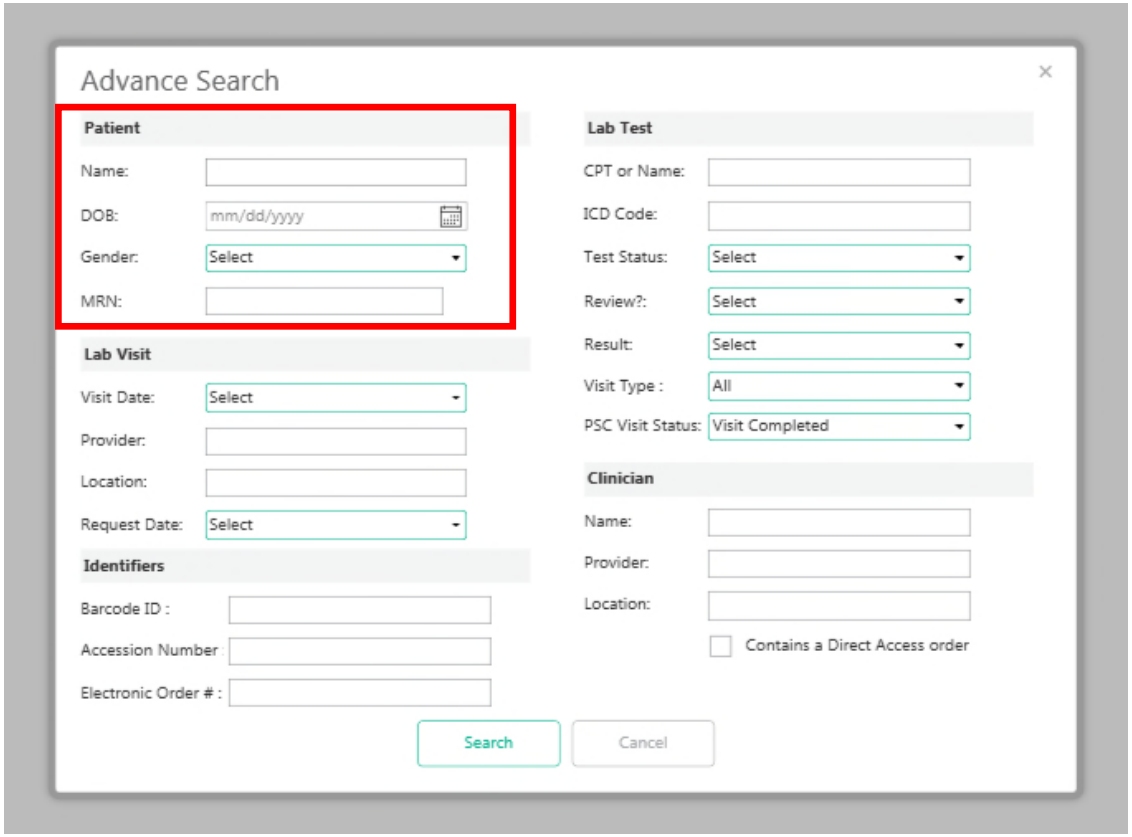
AK31 Container ID
Anam Khan, 6/24/2015

AK32 unique visit-specific ID #
Anam Khan, 6/24/2015

AK33 Patient ordered
Anam Khan, 6/24/2015

Searching for Accessions

Searching for Patient Requisitions by Patient Information

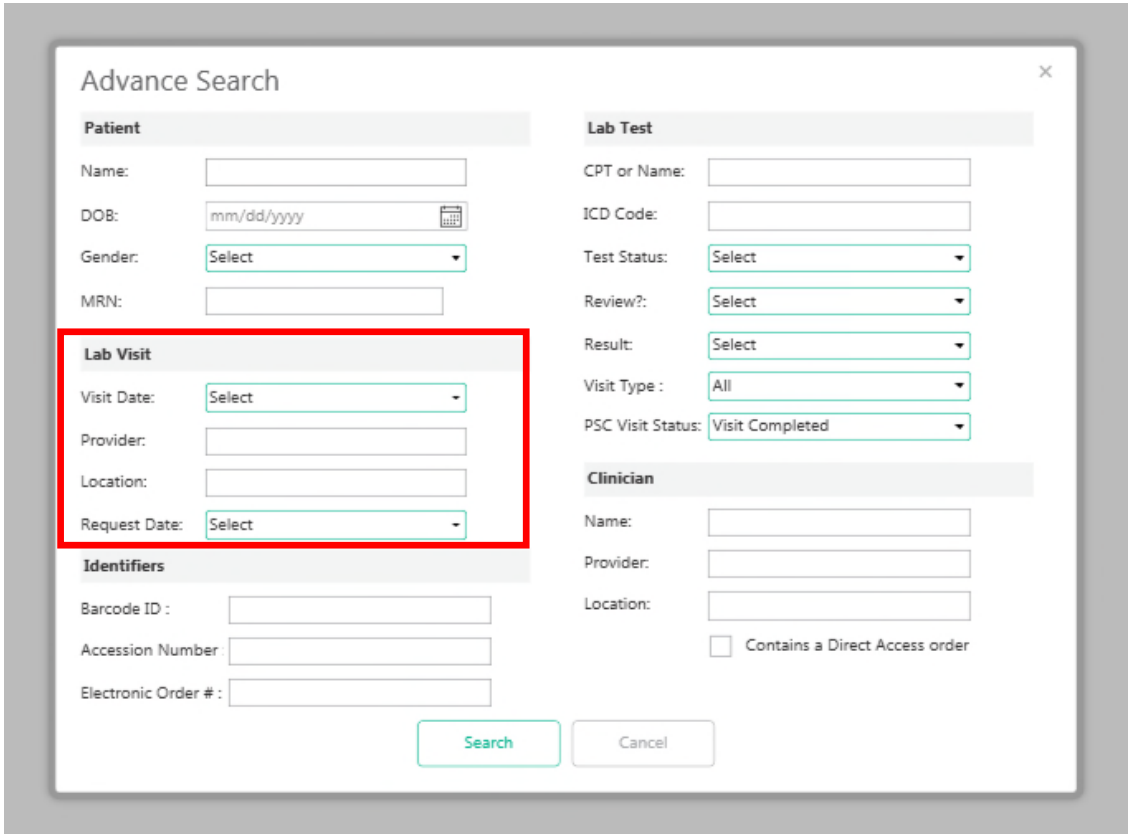


Users can search for accessions by patient information:

- Name
- DOB
- Gender
- MRN

Searching for Accessions

Searching for Patient Requisitions by Visit Date



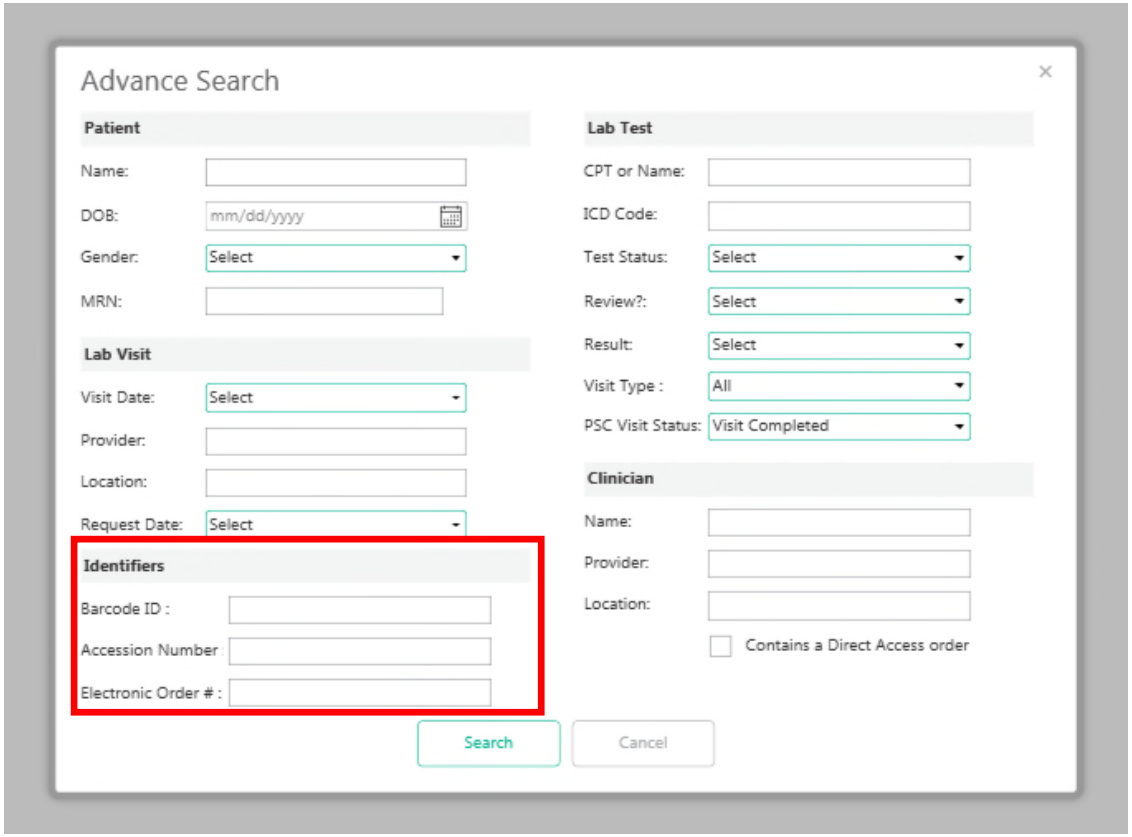
By lab visit information:

- Visit Date
- Provider Name
- Location Name
- Request Date

* To search by Walgreens location:
-Select 'Walgreens' as the Provider
-Select the specific Walgreens store as the Location.

Searching for Accessions

Searching for Patient Requisitions by Visit-specific Information

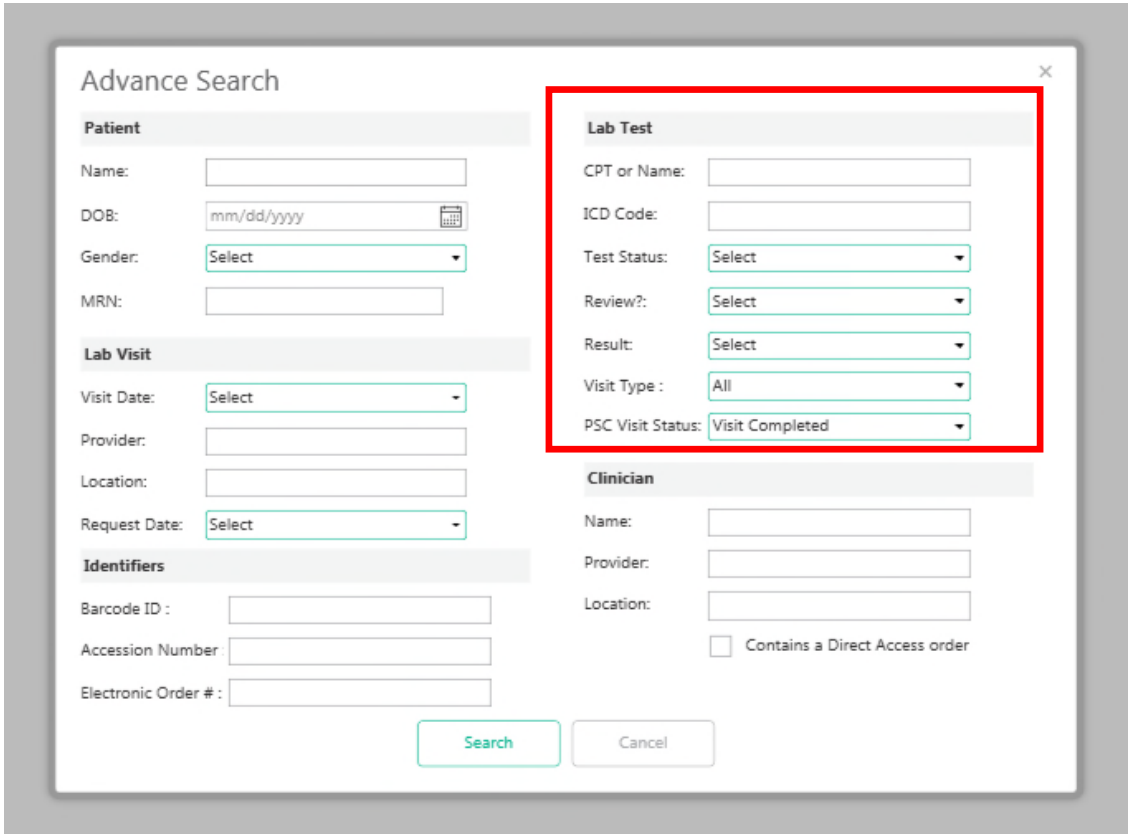


By visit- specific information:

- Container Barcode ID
- Accession #
- Electronic Order #

Searching for Accessions

Searching for Patient Requisitions by Test Name/ CPT Code

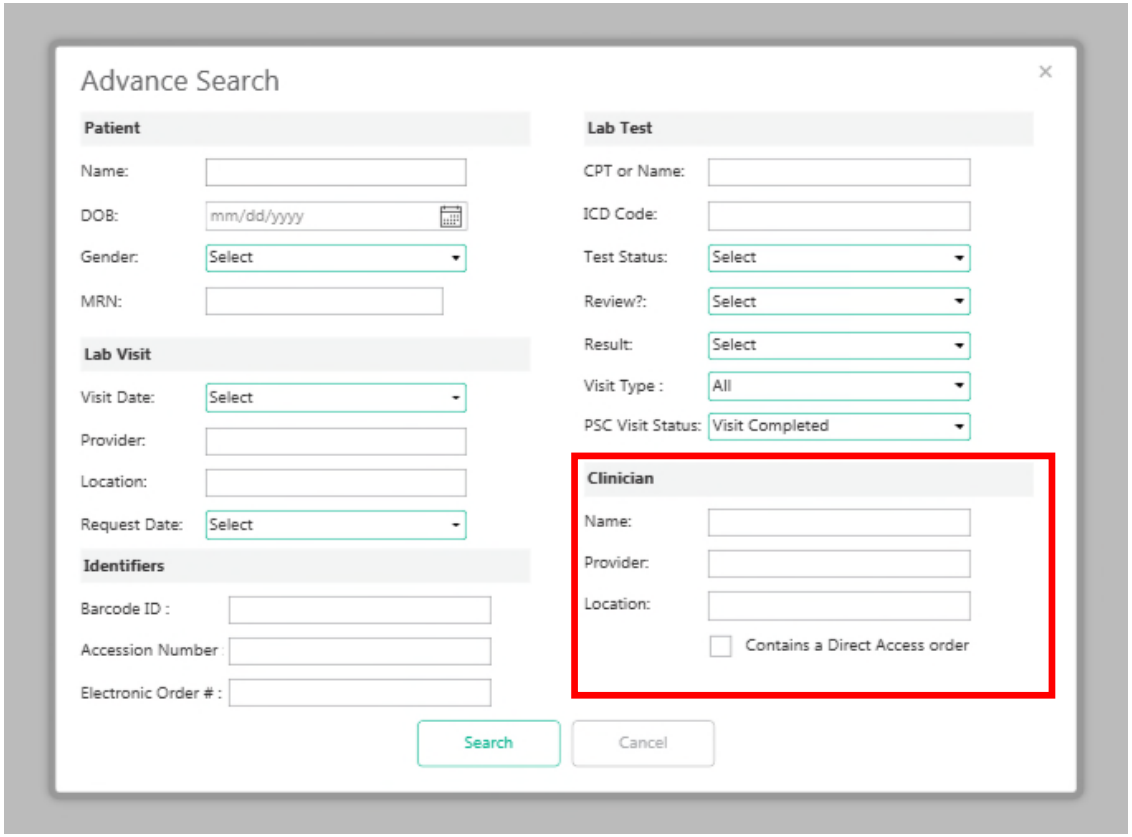


By Lab Test information:

- CPT or Test Name
- ICD-9 Code
- Test Status
- Result/Flag Type
- Visit Type
- PSC Visit Status

Searching for Accessions

Searching for Patient Requisitions by Provider/Clinician

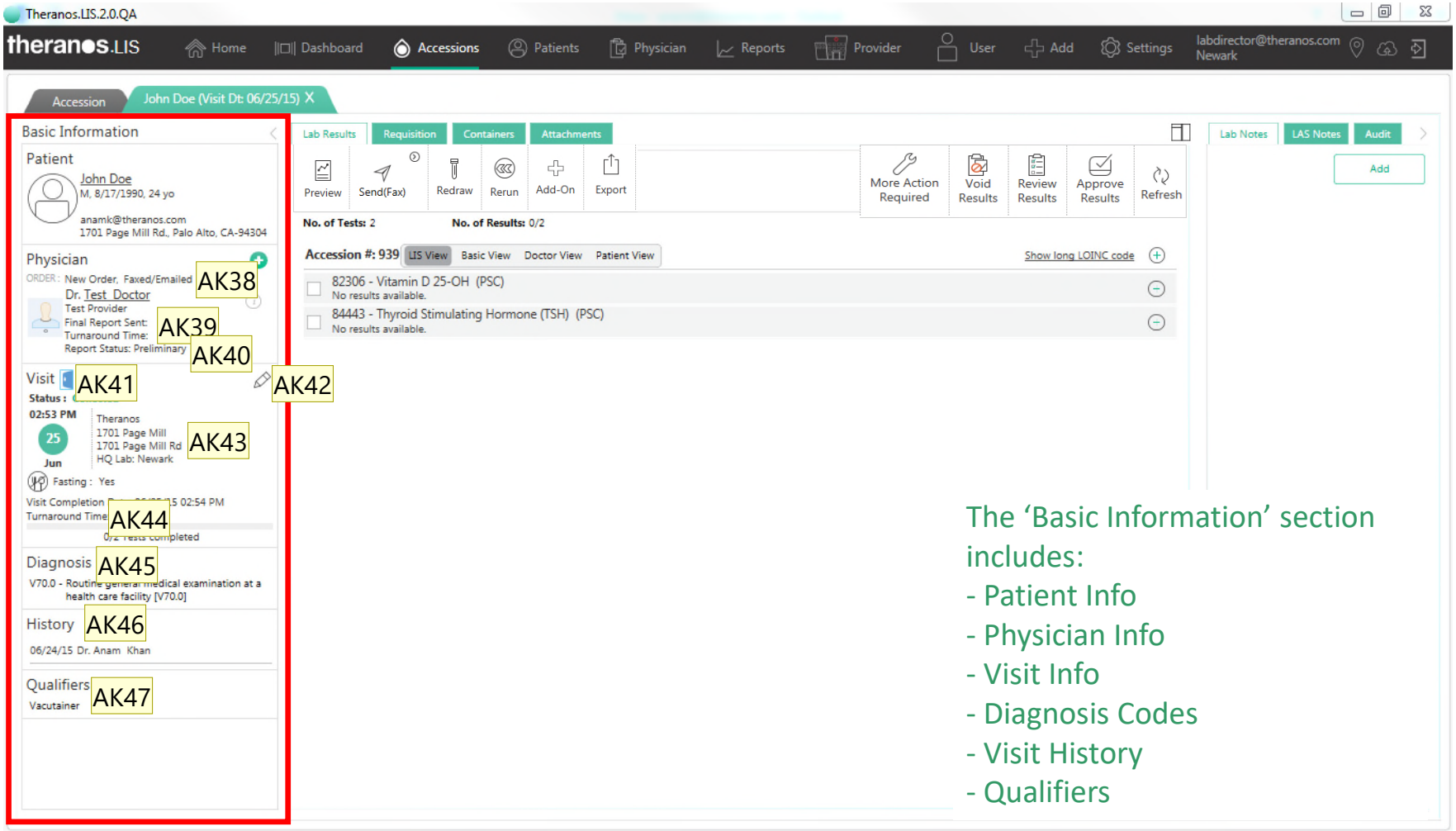


Or by Clinician information:

- Clinician Name
- Clinician Provider
- Clinician Location

Completed Accessions

Visit Screen- Basic Information



The 'Basic Information' section includes:

- Patient Info
- Physician Info
- Visit Info
- Diagnosis Codes
- Visit History
- Qualifiers

Slide 35

AK38 Order- type of order, electronic vs paper vs .ME
Anam Khan, 6/25/2015

AK39 If there are multiple physicians, this shows when each report was sent
Anam Khan, 6/25/2015

AK40 Visit status based on which tests have been sent to physician
Anam Khan, 6/25/2015

AK41 Indicates whether the visit is Open(pending) or closed (completed).
Anam Khan, 6/25/2015

AK42 Edit visit or containers
Anam Khan, 6/25/2015

AK43 PSC location info
Anam Khan, 6/25/2015

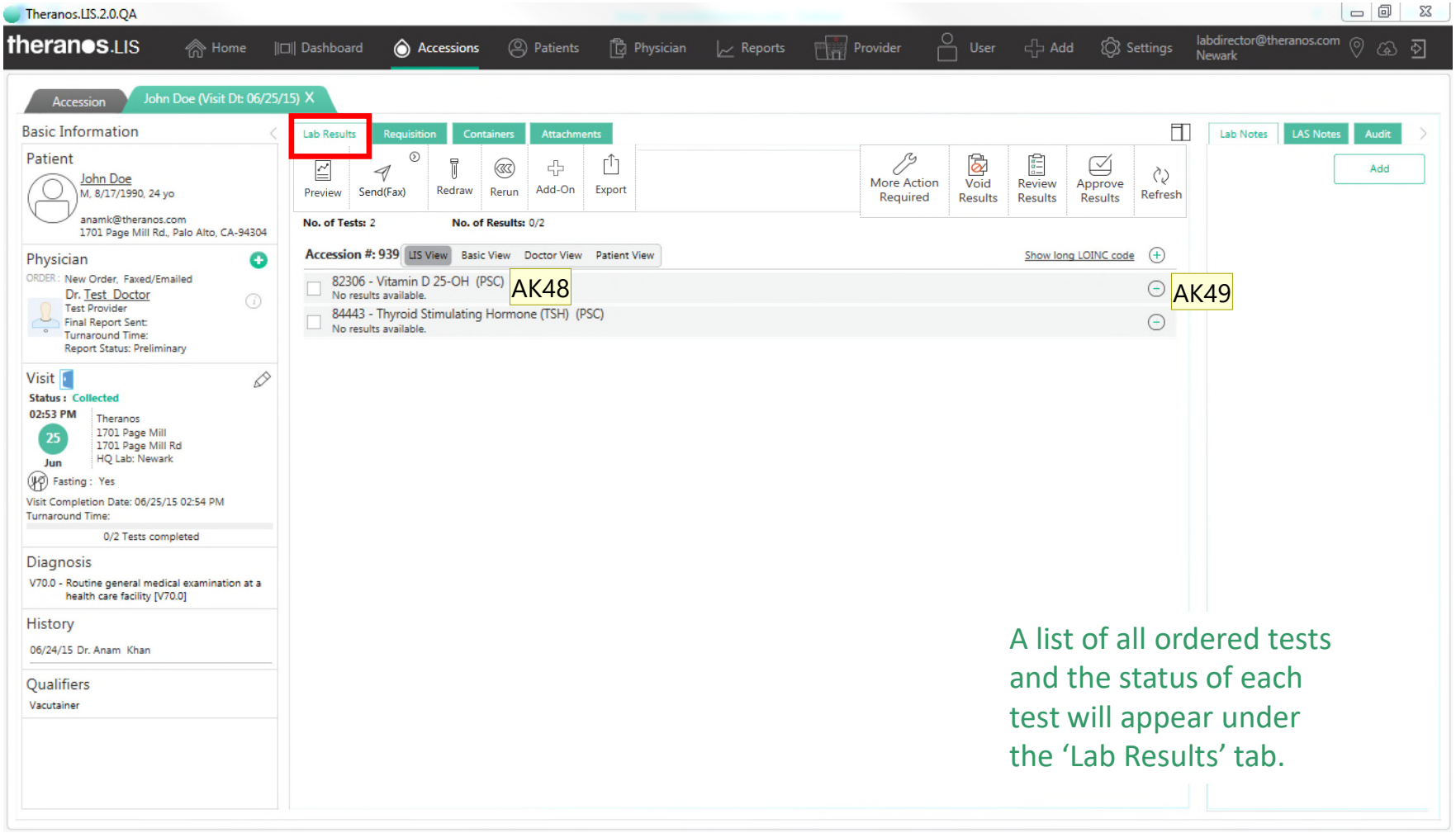
AK44 TAT- time visit is completed to when results are released to the first physician
Anam Khan, 6/25/2015

AK45 Diagnostic codes used for submitting claims to insurance
Anam Khan, 6/25/2015

AK46 A list of the patient's most recent visits
Anam Khan, 6/25/2015

AK47 Type of collection
Anam Khan, 6/25/2015

Visit Screen- Lab Results Tab



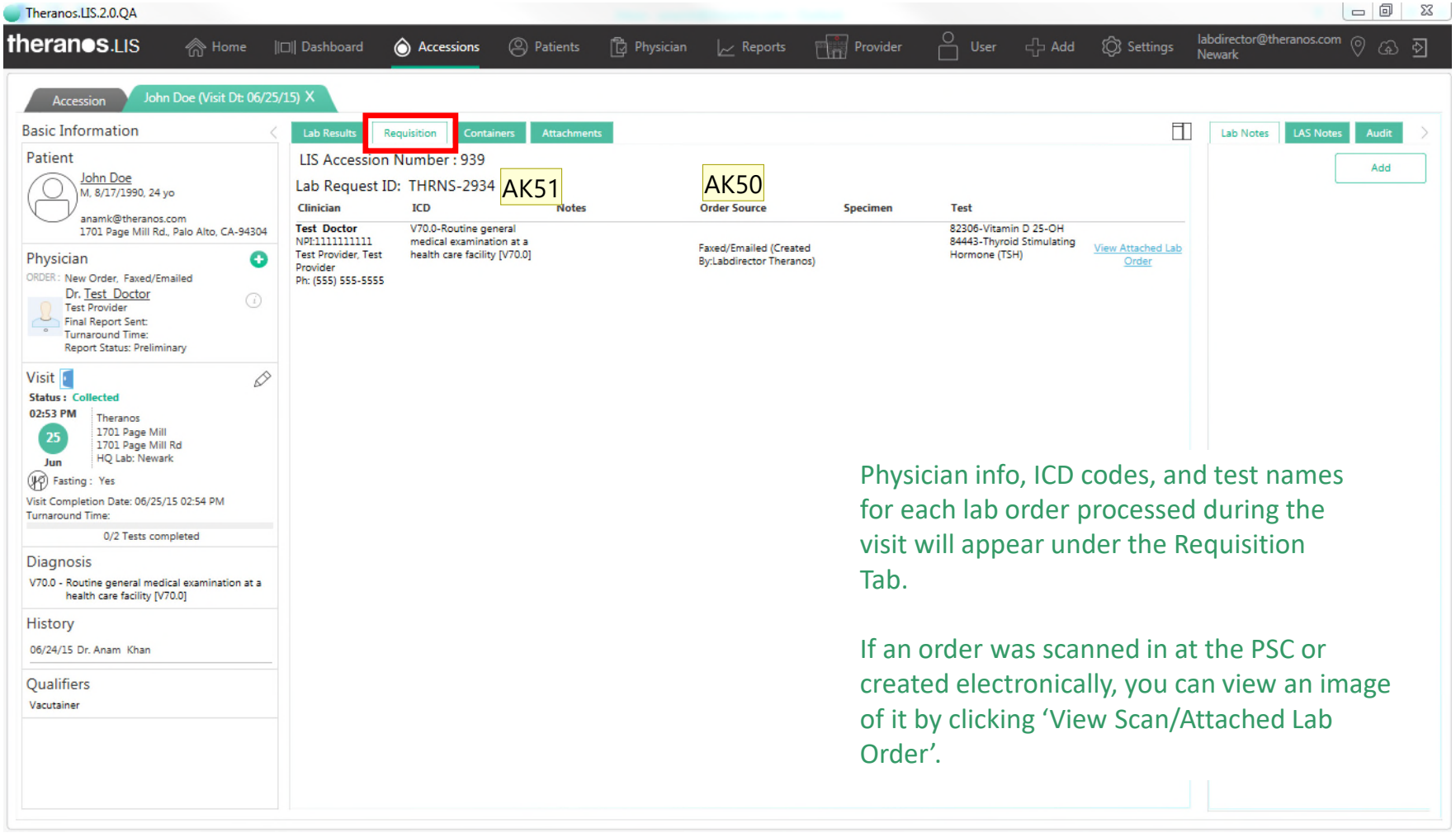
A list of all ordered tests and the status of each test will appear under the 'Lab Results' tab.

Slide 36

AK48 Names and status of each test
Anam Khan, 6/25/2015

AK49 Clicking the plus sign expands each test so you can enter results, view RR, and change status
Anam Khan, 6/25/2015

Visit Screen- Requisition Tab



Physician info, ICD codes, and test names for each lab order processed during the visit will appear under the Requisition Tab.

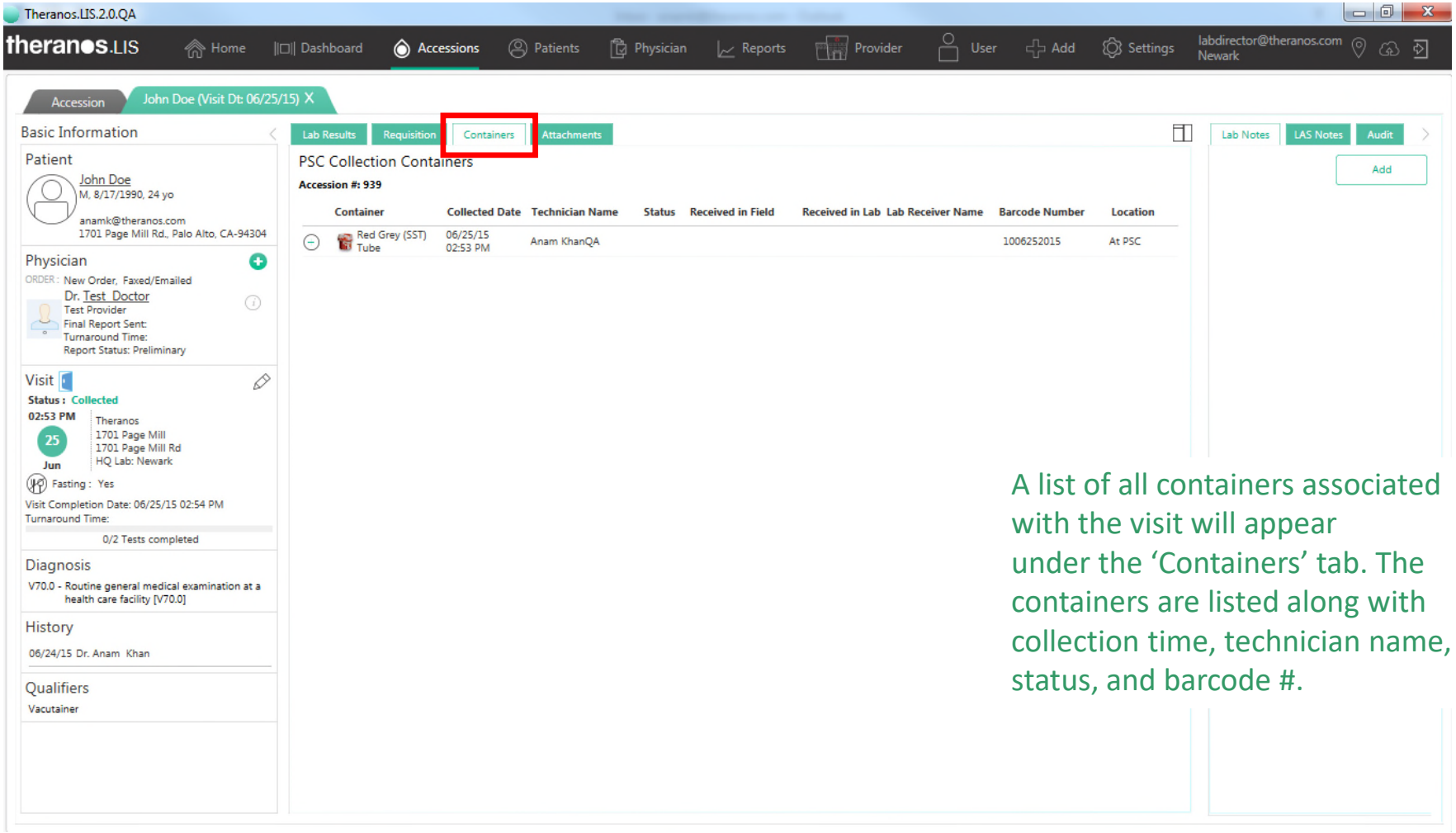
If an order was scanned in at the PSC or created electronically, you can view an image of it by clicking 'View Scan/Attached Lab Order'.

Slide 37

AK50 Where the order generated
Anam Khan, 6/25/2015

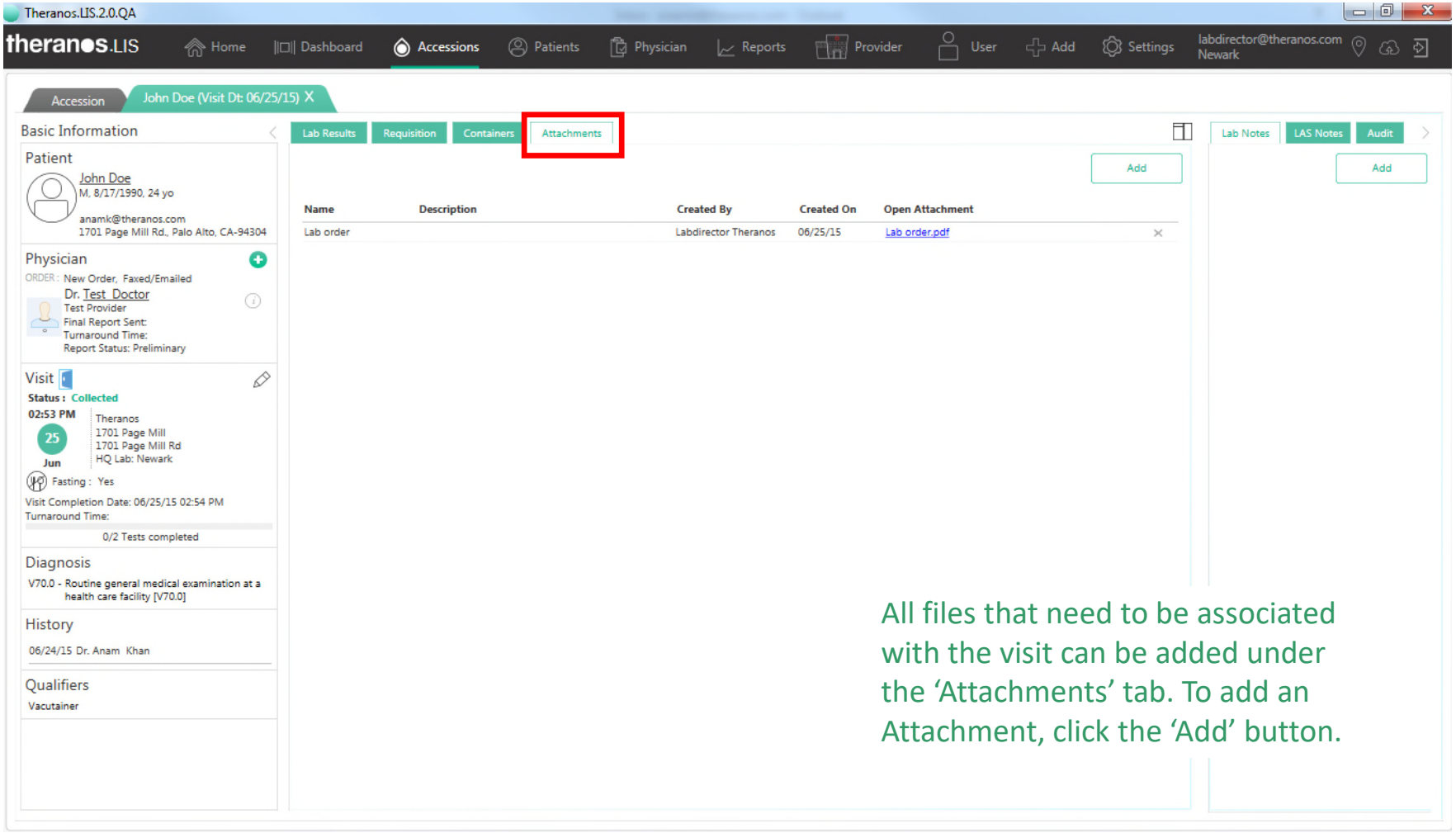
AK51 Order-specific ID, useful when adding CC physicians
Anam Khan, 6/25/2015

Visit Screen- Containers Tab



A list of all containers associated with the visit will appear under the 'Containers' tab. The containers are listed along with collection time, technician name, status, and barcode #.

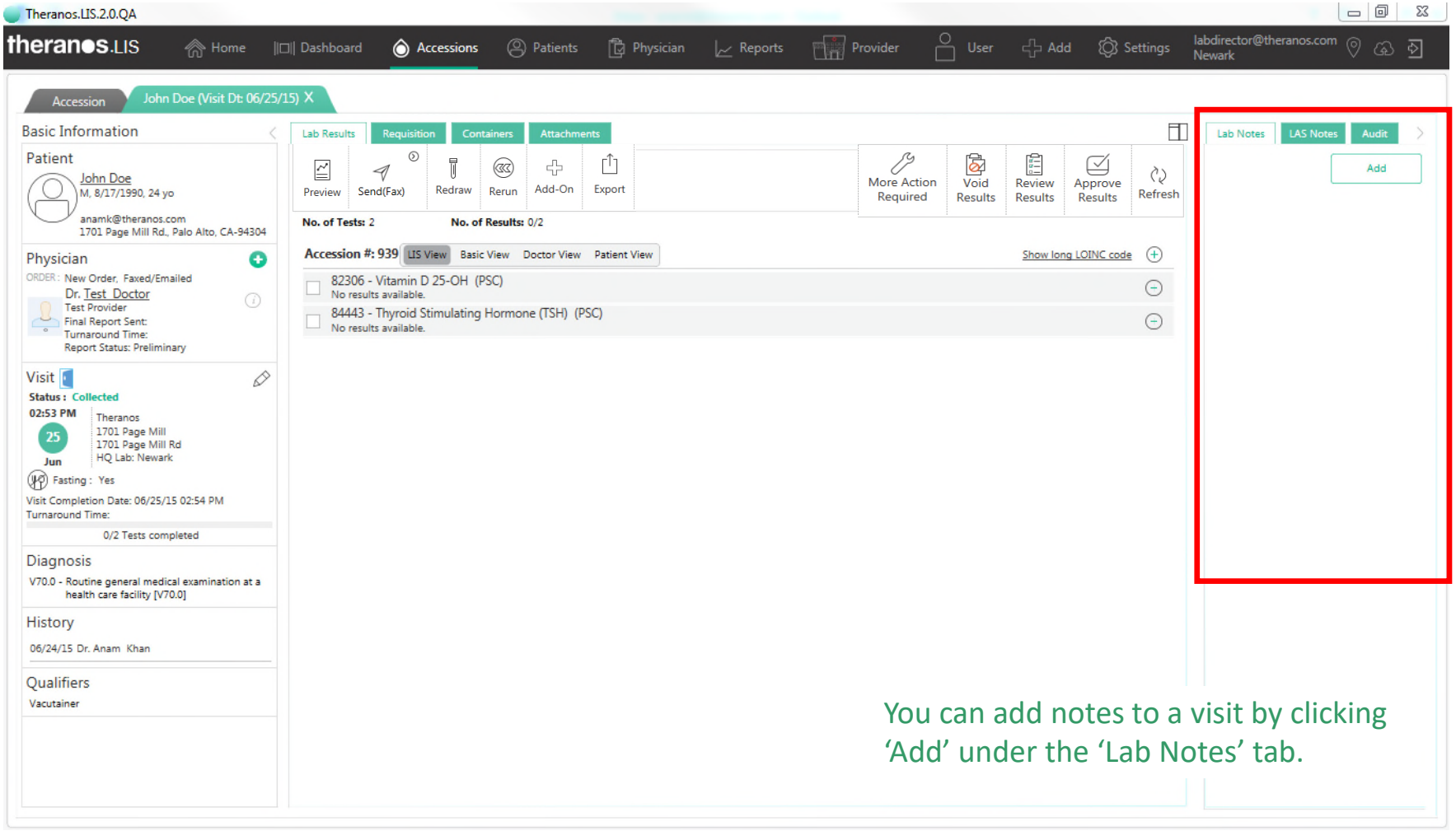
Visit Screen- Attachments Tab



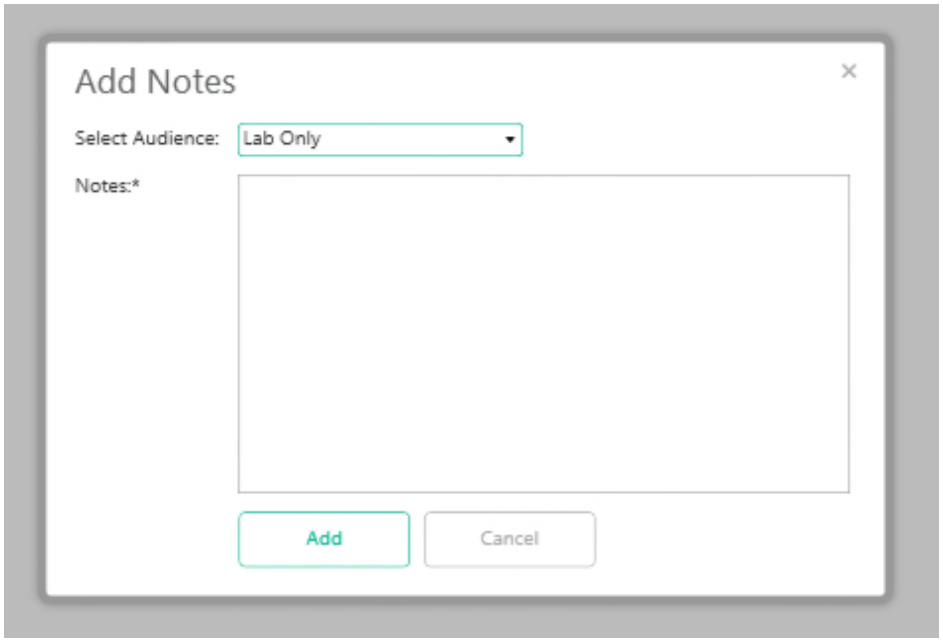
Adding Attachment to Visit

To add an attachment: Click ‘Browse’ to upload an attachment, name the file, then click ‘Save’.

Visit Screen- Lab Notes

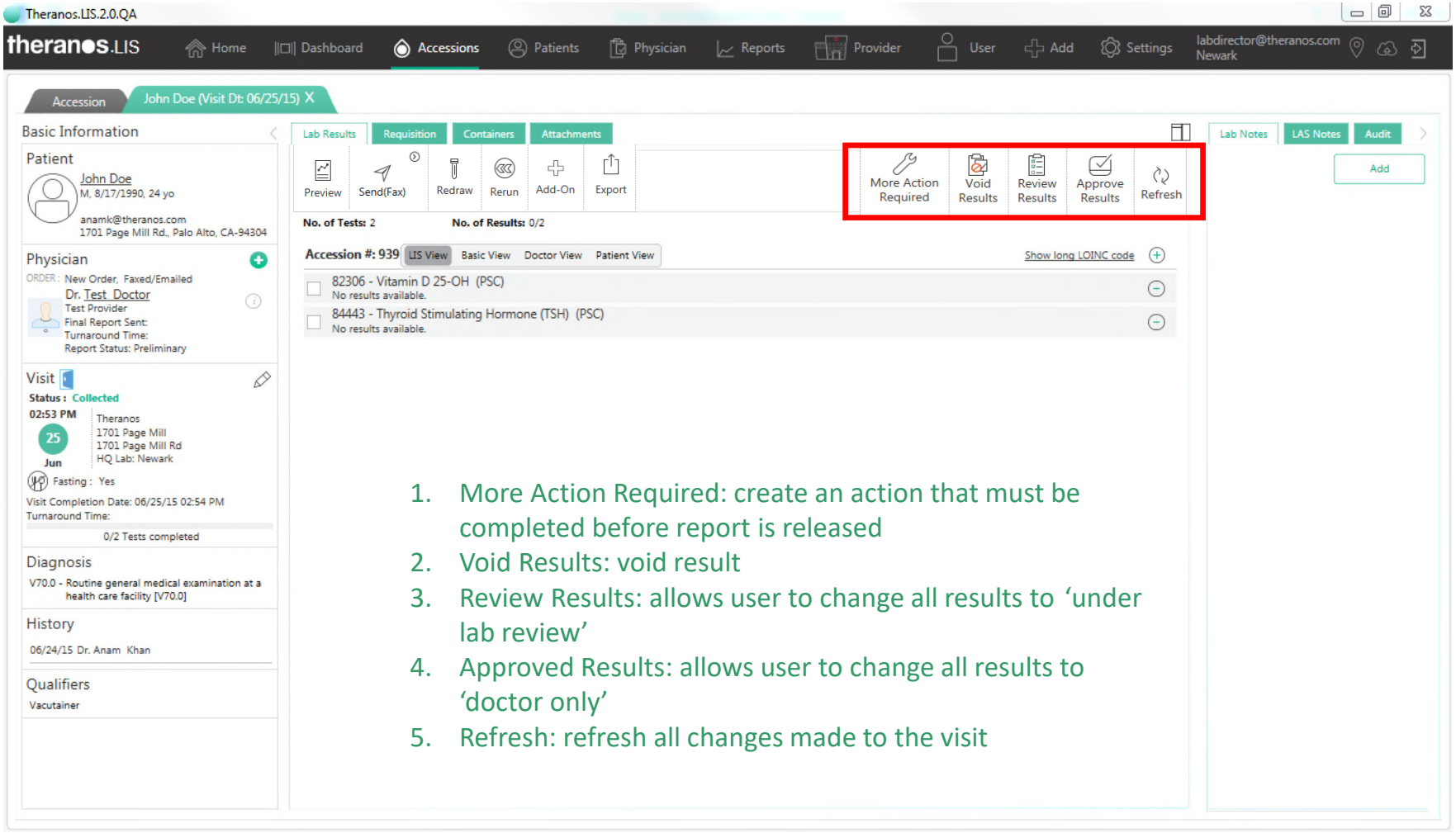


Adding Lab Note to Visit



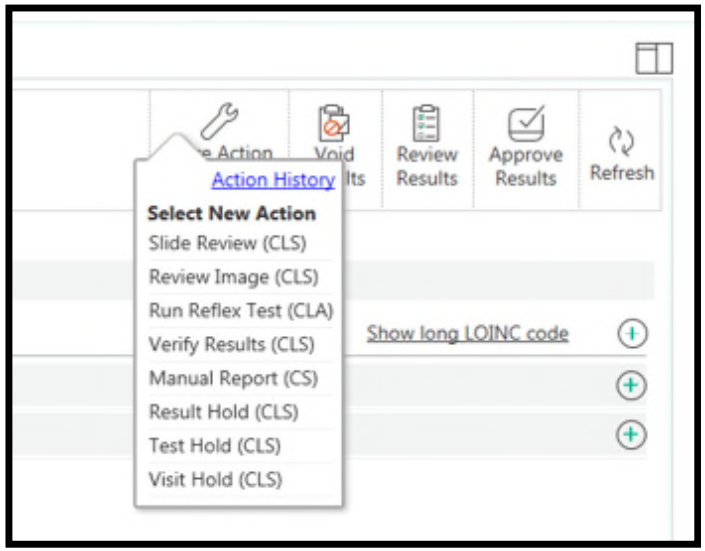
To add a note:
Select 'Lab Only' or 'Physician' from the drop down menu, enter a note, then click 'Add'. Lab Only notes are internal and will only appear in LIS. Physician notes will appear at the bottom of the result report.

Visit Screen- Lab Actions



1. More Action Required: create an action that must be completed before report is released
2. Void Results: void result
3. Review Results: allows user to change all results to 'under lab review'
4. Approved Results: allows user to change all results to 'doctor only'
5. Refresh: refresh all changes made to the visit

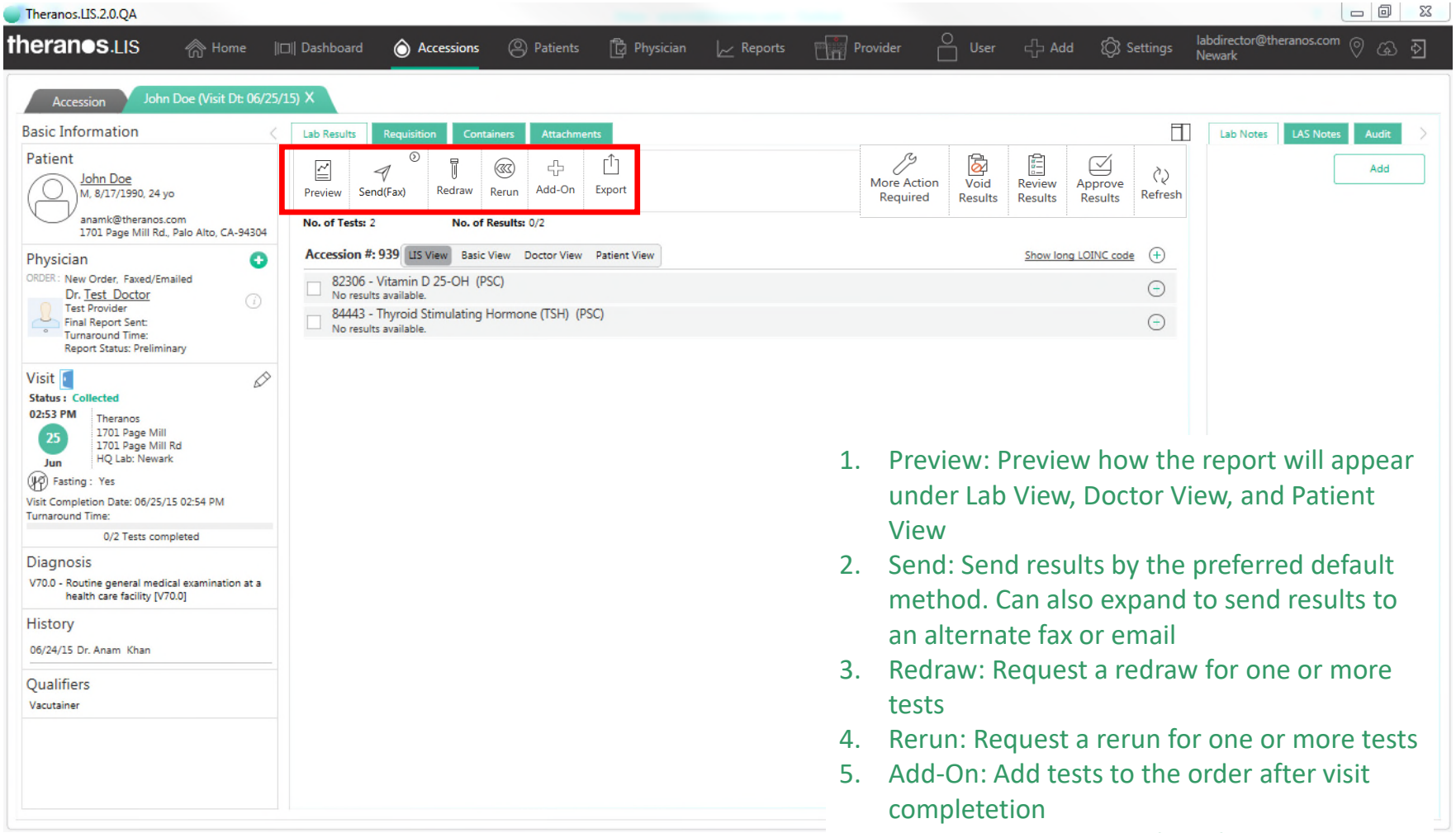
Adding Action to Visit



More Action:

Slide Review- Request CLS to perform slide review
Review Image- Request CLS to Review Image of sample
Run Reflex Test- Request lab to run reflex test
Verify Results- Request CLS to review results
Manual Report- Request CS to make a manual report
Result Hold- Request CLS to put a hold on result
Test Hold- Request CLS to put a hold on test
Visit Hold- Request CLS to put a hold on the visit

Visit Screen- Sending Results



1. Preview: Preview how the report will appear under Lab View, Doctor View, and Patient View
2. Send: Send results by the preferred default method. Can also expand to send results to an alternate fax or email
3. Redraw: Request a redraw for one or more tests
4. Rerun: Request a rerun for one or more tests
5. Add-On: Add tests to the order after visit completetion
6. Export: Export a PDF of the final report

Faxing Results to Physician

Sending Results

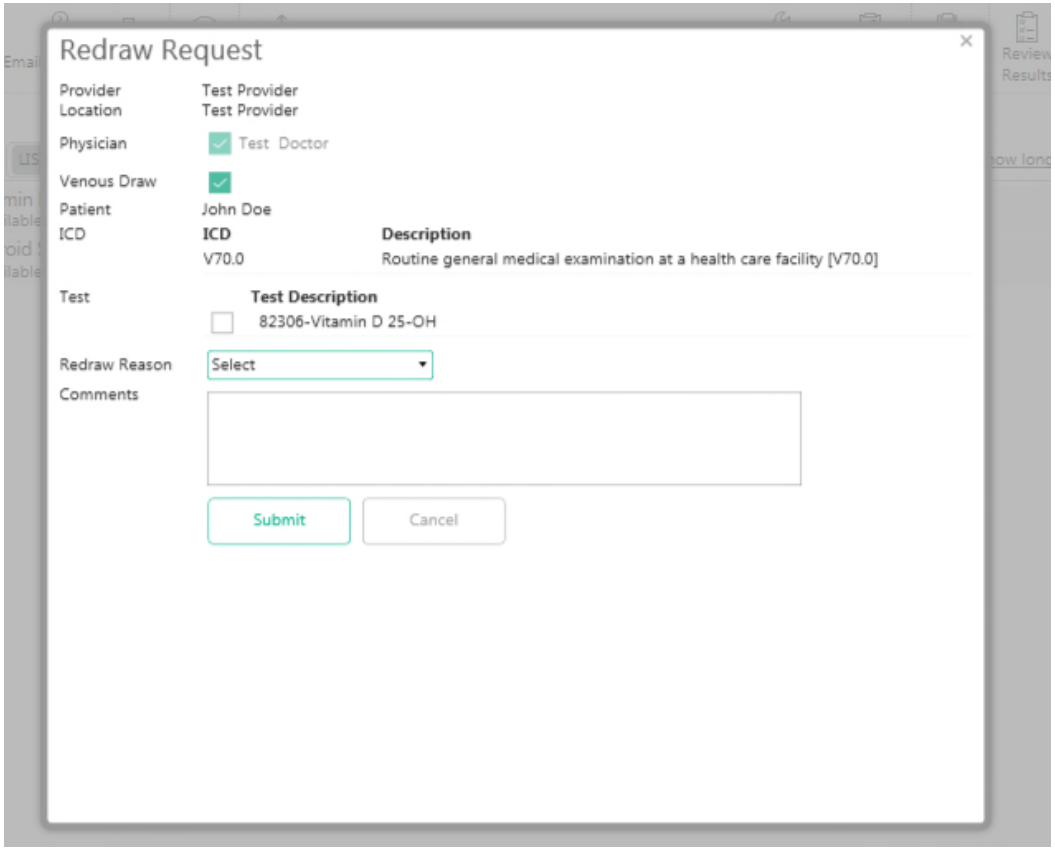
To Fax Results to the Ordering Physician:

1. Select Provider Location from the drop down menu
2. Check off 'Provider Fax' or 'Physician Fax' and select a fax number from the drop down menu
3. Click the 'Preview' button to view a preview of the final report
4. Can also enter in a new fax # to send results to. This number will be linked to the Provider location going forward.
5. Click 'Send Fax' to fax the results to the physician

To Fax Results to a Copy-to Physician:

1. Type in the Provider Name, Location Name, and Doctor's Name in the appropriate fields
2. Check off 'Provider Fax' or 'Physician Fax' and select a fax number from the drop down menu
3. To add another Copy-to Physician, click the blue '+' sign
4. Click the 'Preview' button to view a preview of the final report
5. Click 'Send Fax' to fax the results to the physician

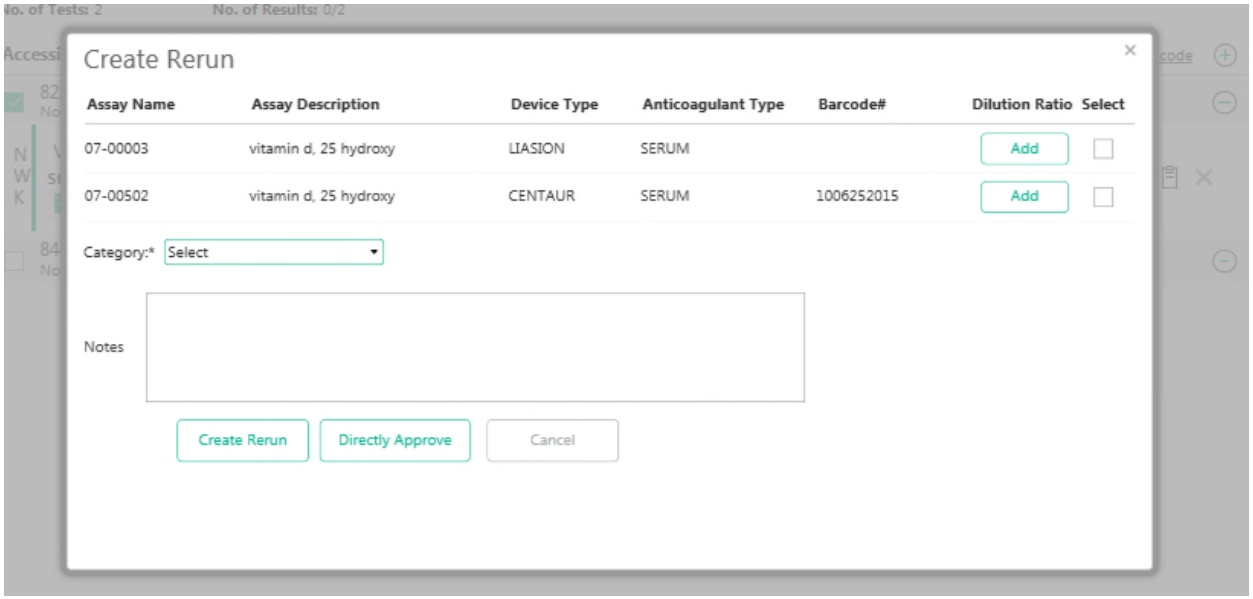
Requesting Redraws



Request Redraw

1. Select tests on the Lab Request screen
2. Click on the Redraw icon and select 'Create New Redraw Request'.
3. If there is more than one physician, check off the correct one.
4. Select the tests that need to be redrawn.
5. Select a Redraw Reason from the drop down menu
6. Enter in any additional comments, then click Submit.
7. The redraw will appear in the Redraw Request list so a Lab Director can approve it.

Requesting Reruns



Request a Re-run

1. Select tests on the Lab Request screen
2. Click on the Rerun icon and select ‘Create New Rerun’.
3. Select the device method the test should be rerun on.
4. Select a Rerun Category from the drop down menu
5. Enter in any additional comments, then click ‘Create Rerun’ or ‘Directly Approve’.

Add-on Tests

Add on Tests:

At a physician's request, users can add tests to an order after visit completion. The application will determine if the test(s) can be added based on:

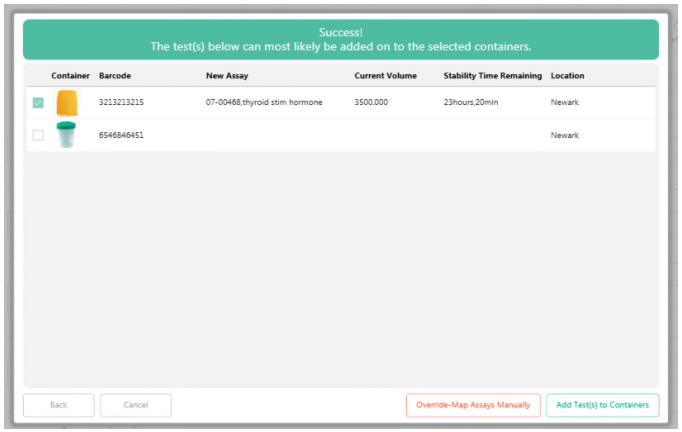
- Stability time remaining for the assay
- Anticoagulant match
- Estimated volume remaining

To request an add-on:

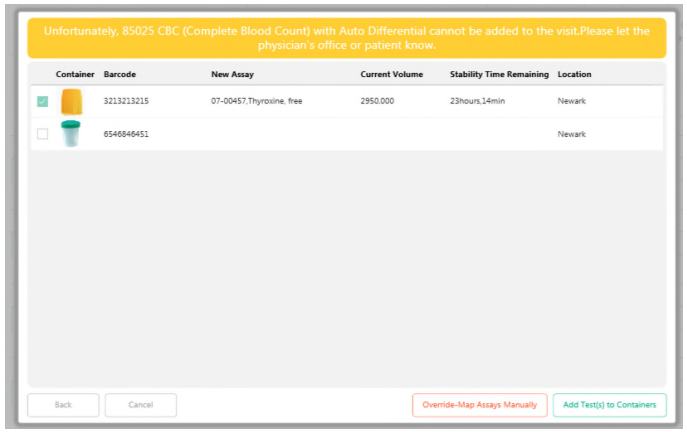
1. Select the test(s) that need to be added
2. Select the physician/order the test(s) will be added to
3. Add any ICD codes (if applicable)
4. Click **Next**

Add-on Tests

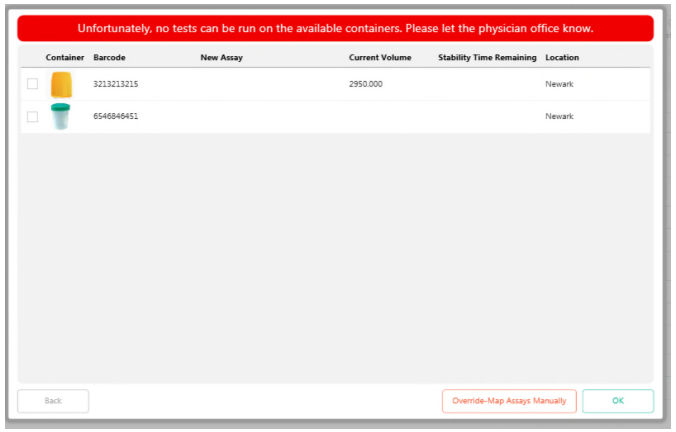
The application will prompt one of the following things:



A green message lets the user know the add-on can most likely be performed. The application will select the default container and display the new assay that's being added on, the current volume remaining, and the stability time remaining for the new add-on assay.

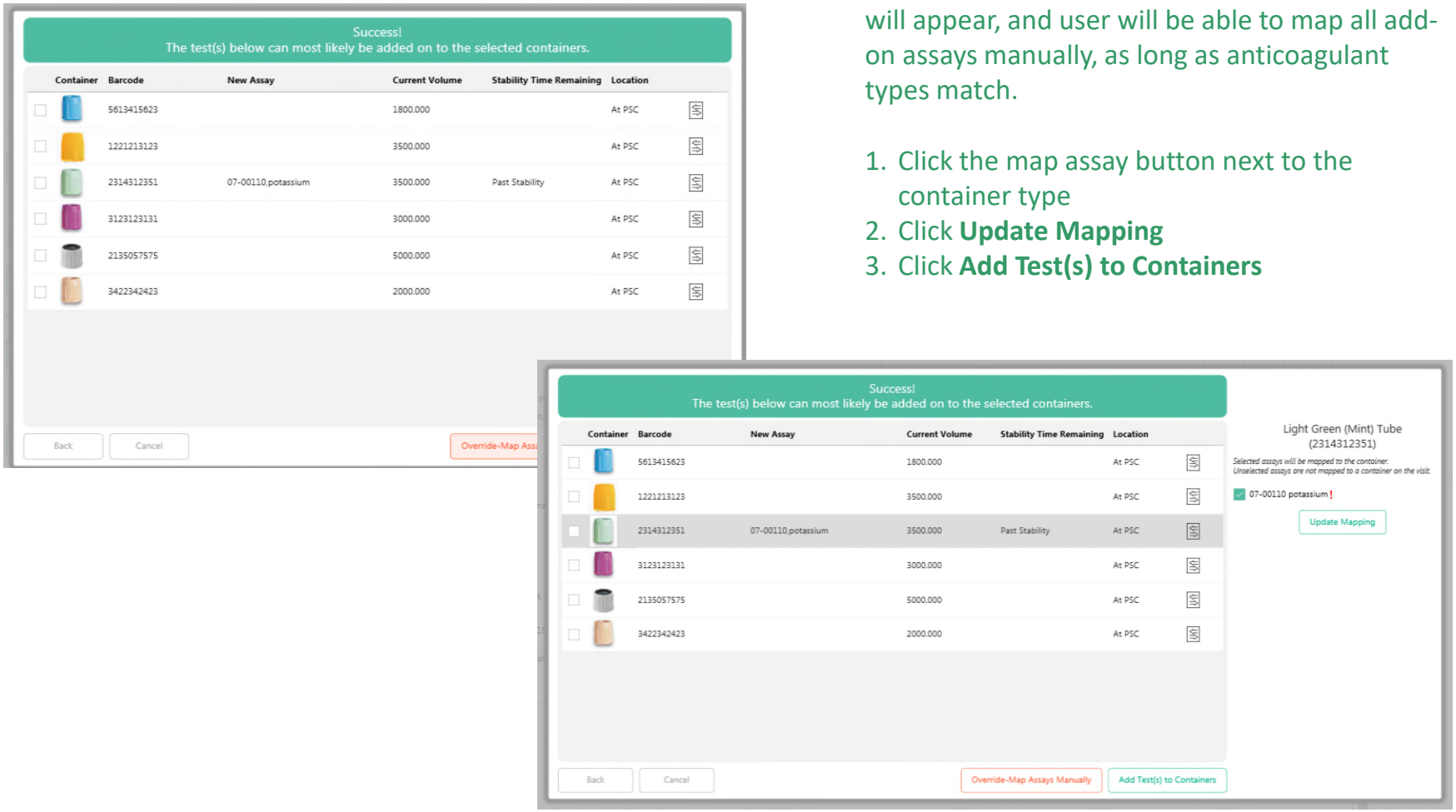


A yellow message lets the user know some assays can be added on, but others cannot.



A red message lets the user know none of the add-ons can be performed. If the reason for this is that the assay is past stability or there is not enough volume, users will be able to use the Override-Map Assays Manually functionality. If the reason is because there is no container with the required anticoagulant type on the visit, it will not be possible to override.

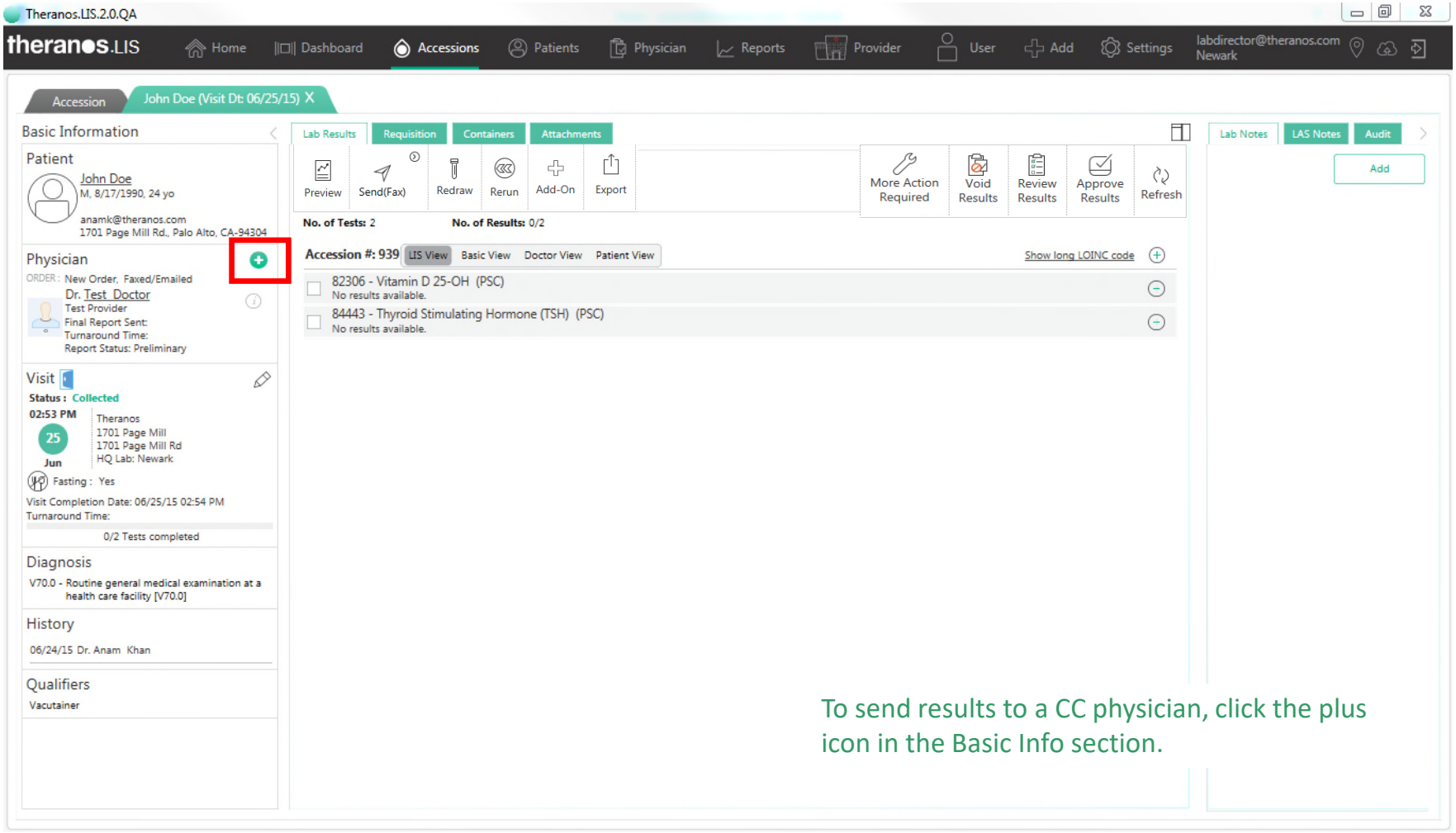
Add-on Tests



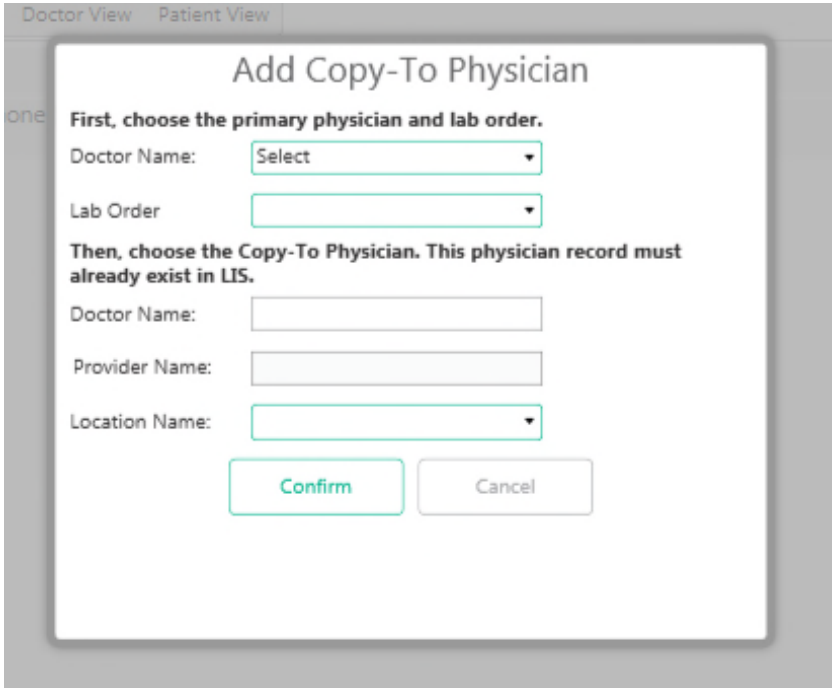
When clicking Override, the map assay buttons will appear, and user will be able to map all add-on assays manually, as long as anticoagulant types match.

1. Click the map assay button next to the container type
2. Click **Update Mapping**
3. Click **Add Test(s) to Containers**

Visit Screen- Copy-to Physician



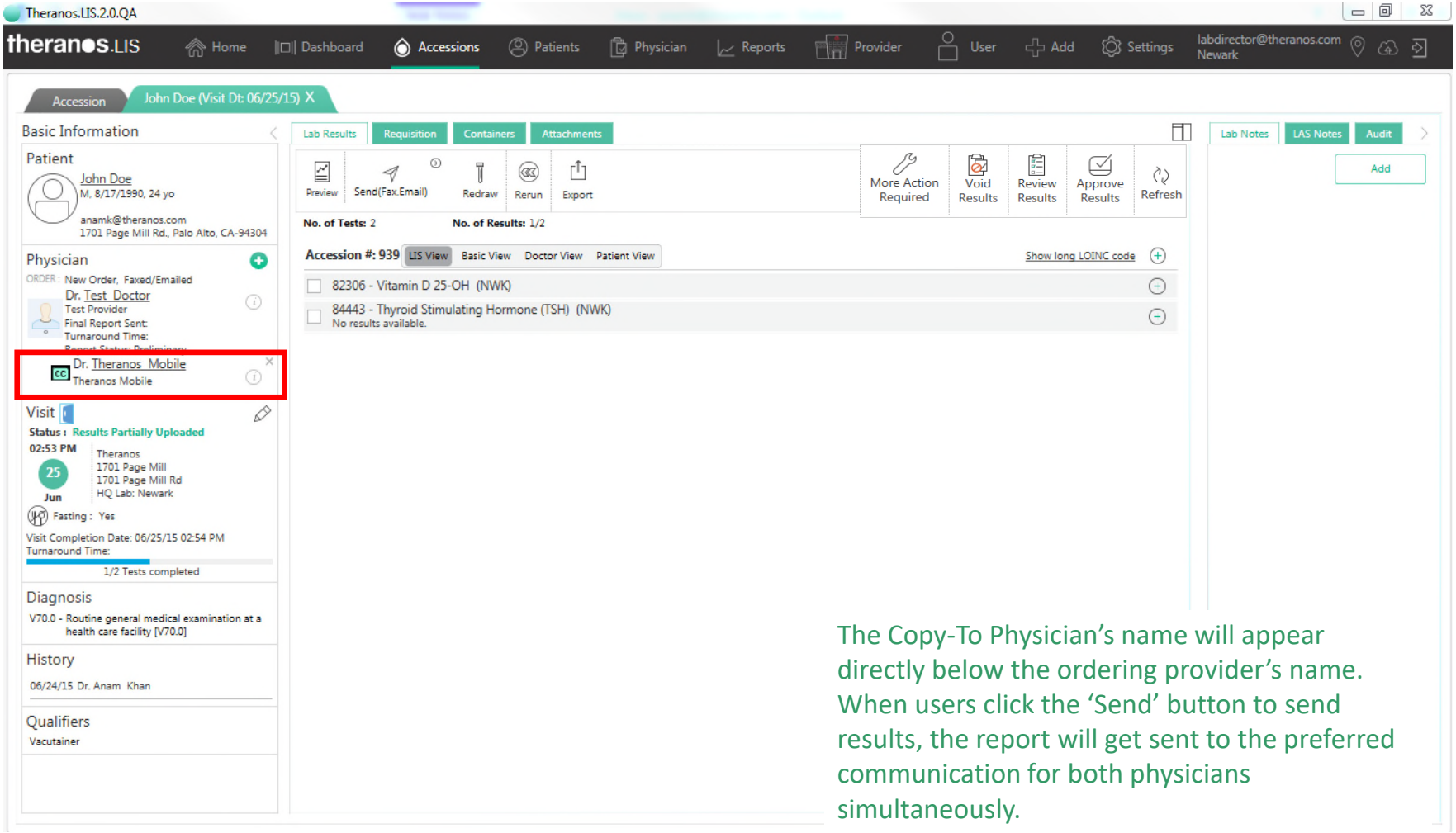
Adding Copy-To Physician to Visit



Add Copy-To Physician:

1. Select the ordering provider's name from the drop down menu
2. Select the Lab Order # from the drop down menu
   - This is especially useful if there are multiple physicians and multiple orders.
3. Select the copy-to physician's name from the drop down menu
4. The Provider and Location name should auto-populate
5. Click 'Confirm'

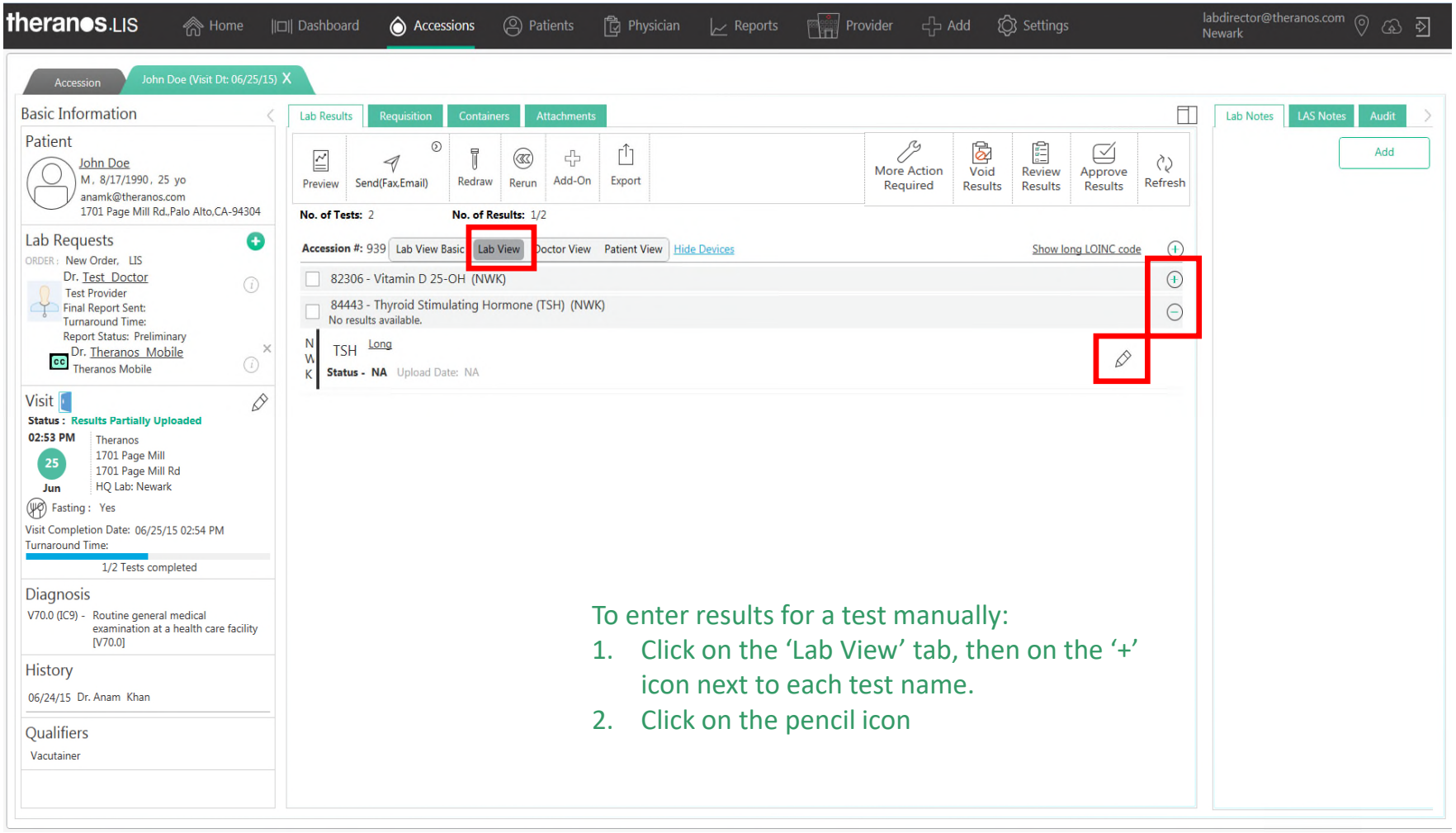
Adding Copy-To Physician to Visit



The Copy-To Physician's name will appear directly below the ordering provider's name. When users click the 'Send' button to send results, the report will get sent to the preferred communication for both physicians simultaneously.

Entering Results

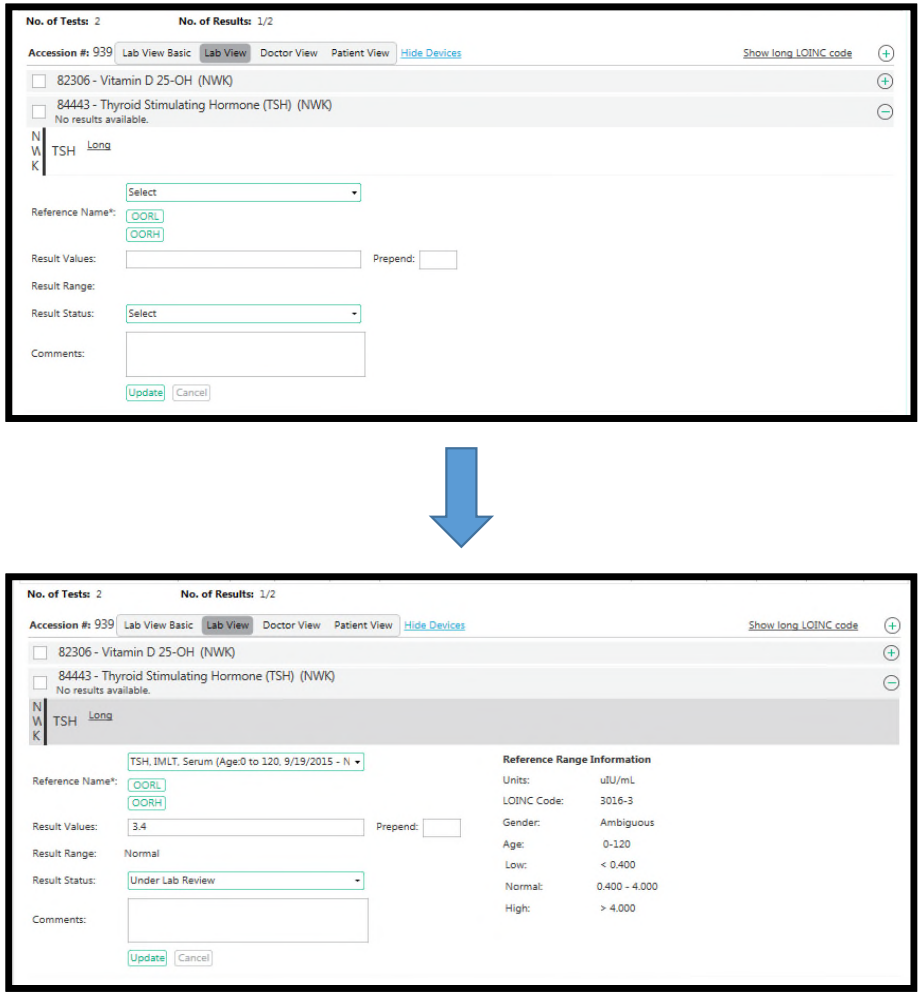
Entering Results



To enter results for a test manually:

1. Click on the 'Lab View' tab, then on the '+' icon next to each test name.
2. Click on the pencil icon

Entering Results



3. Select a Reference Range from the Reference Name drop down menu

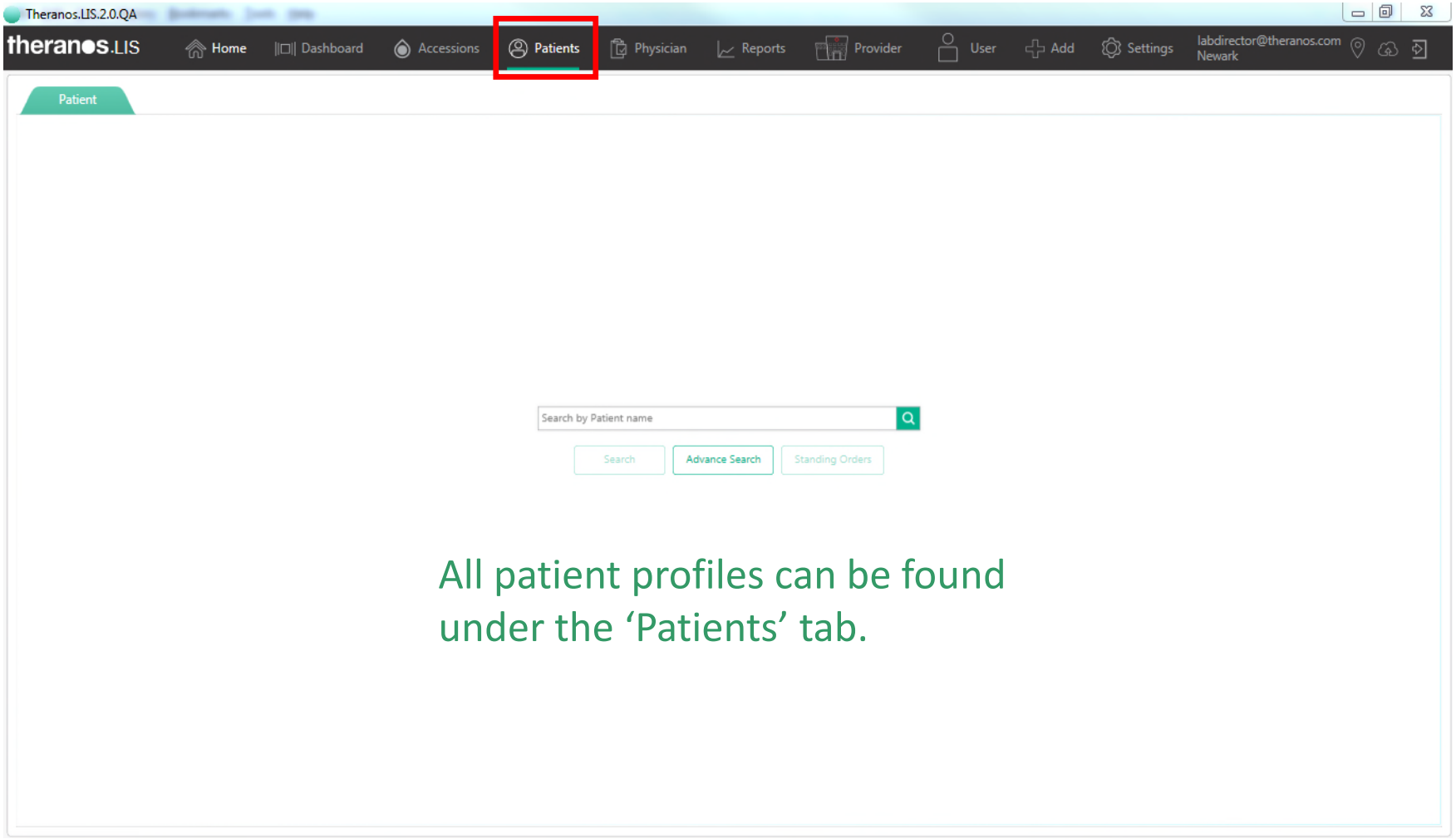
4. Enter the result in the Result Value field. If necessary, enter in a Prepend (> or <). If you click OORL or OORH, the result field will auto-populate with the correct value based on analyte

5. Select a status from the Result Status drop down menu
- Under Lab Review- needs CLS approval
- Doctor Only- approved by CLS, but not sent
- Void by Lab- cannot be released
- Available- available on .ME

6. Click 'Update'

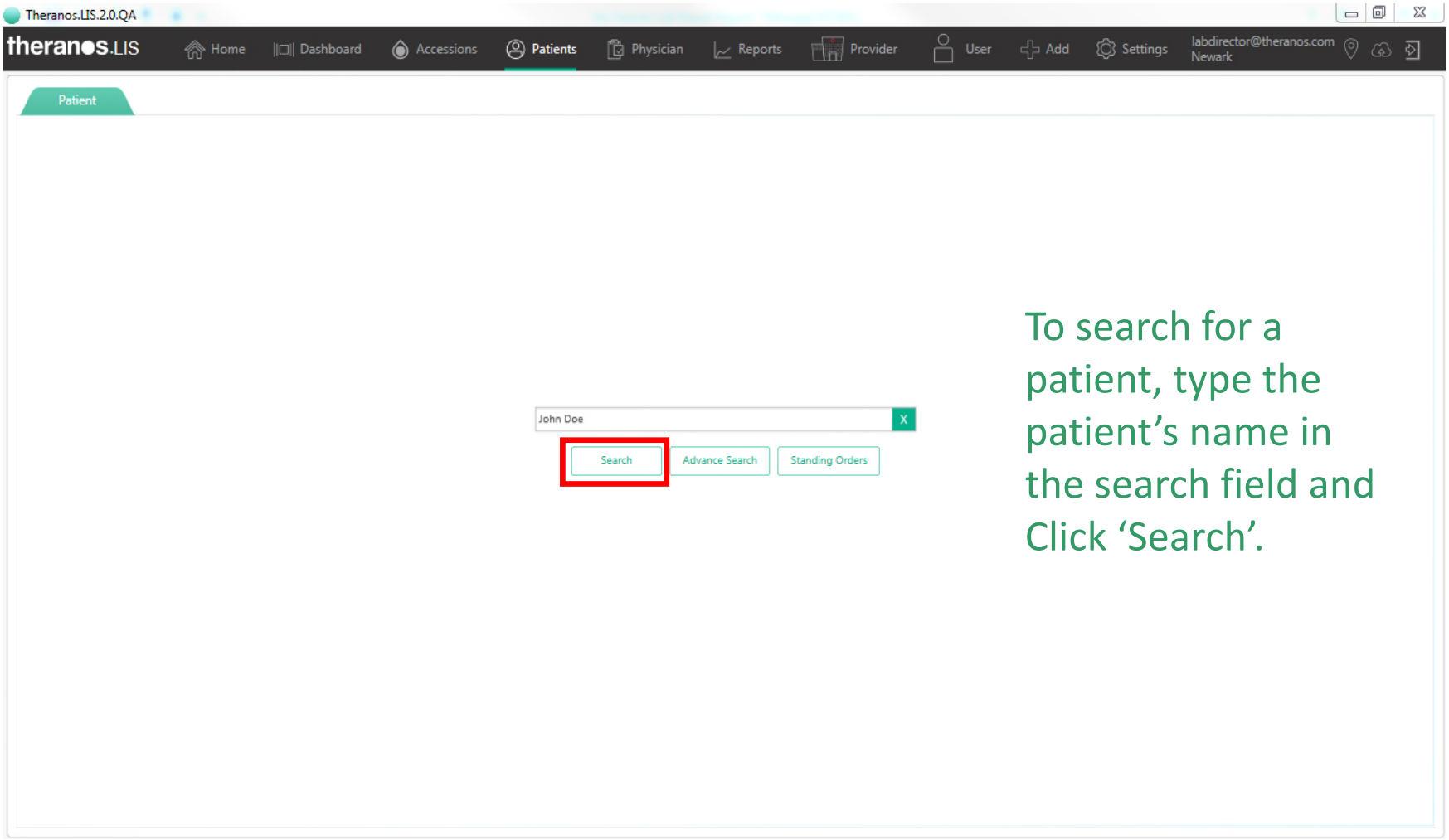
Patient Tab

Searching for Patients



All patient profiles can be found under the 'Patients' tab.

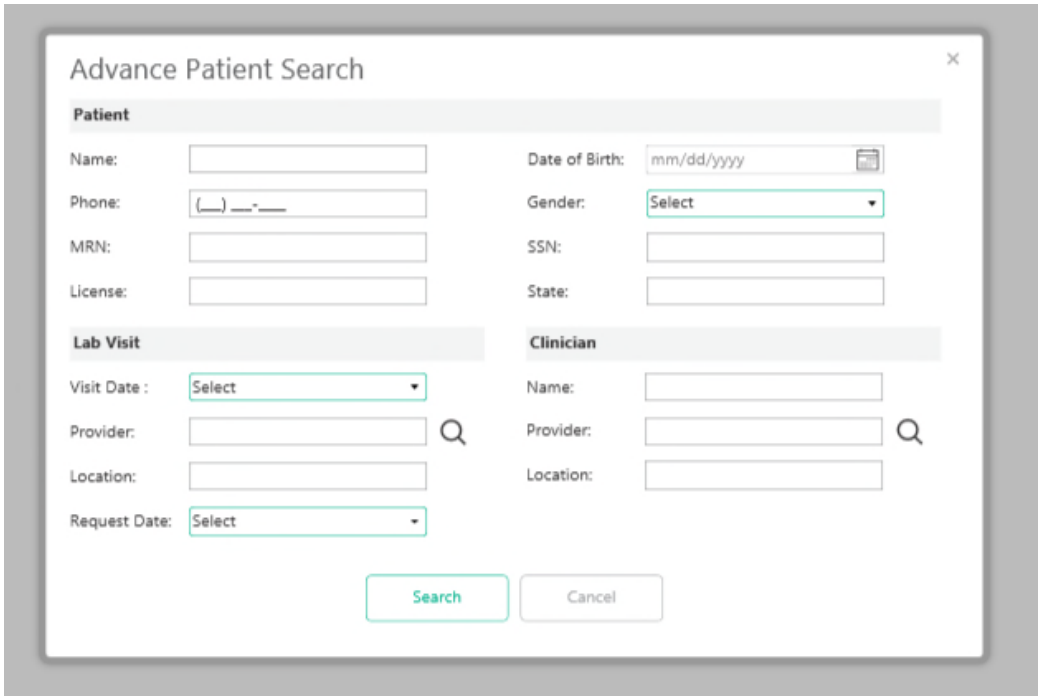
Searching for Patients



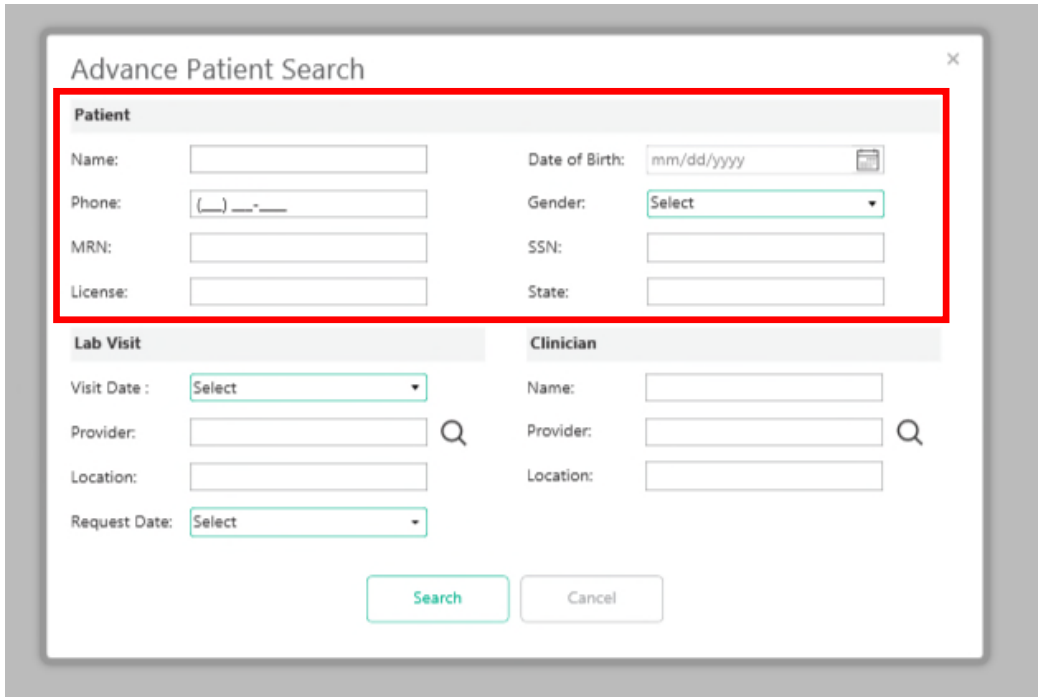
To search for a patient, type the patient's name in the search field and Click 'Search'.

Searching for Patients

Clicking 'Advanced Search' allows the user to search for patient's with specific parameters.



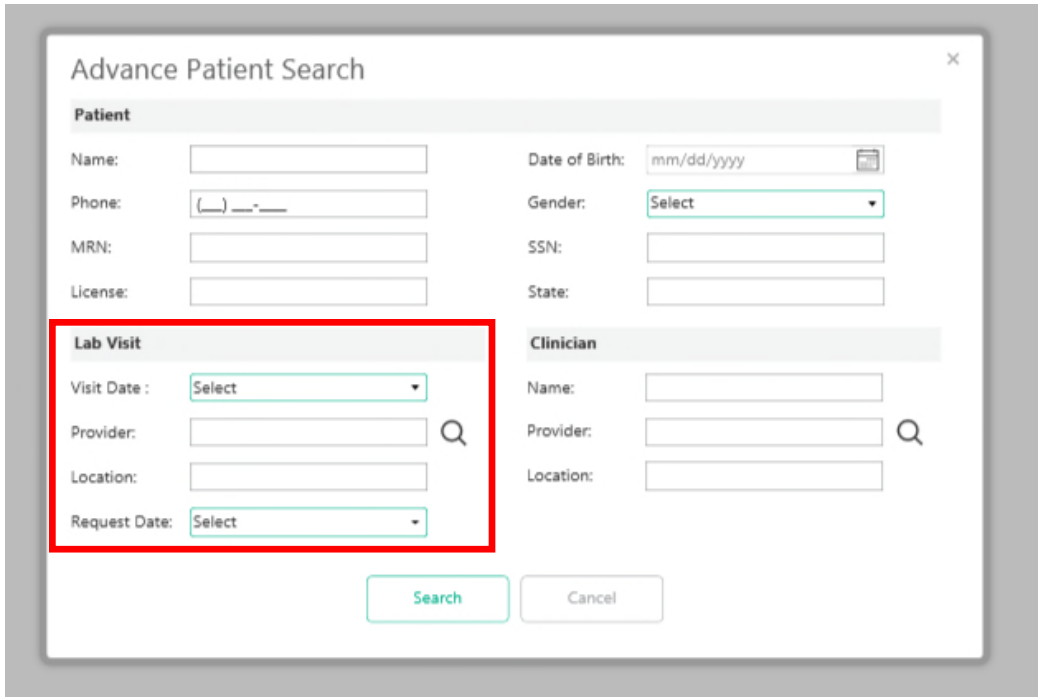
Searching for Patients



Users can search for patient profiles by patient information:

- Name
- DOB
- Phone #
- Gender
- MRN
- SSN
- License
- State

Searching for Patients

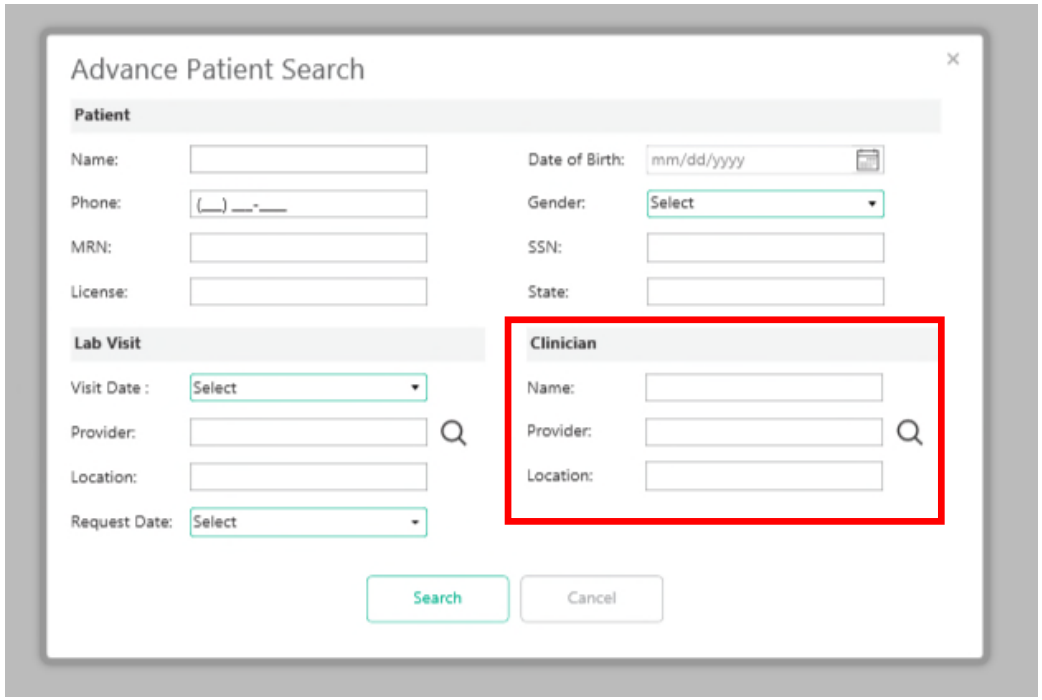


By lab visit information:

- Visit Date
- Provider Name
- Location Name
- Request Date

* To search by Walgreens location:
-Select 'Walgreens' as the Provider
-Select the specific Walgreens store as the Location.

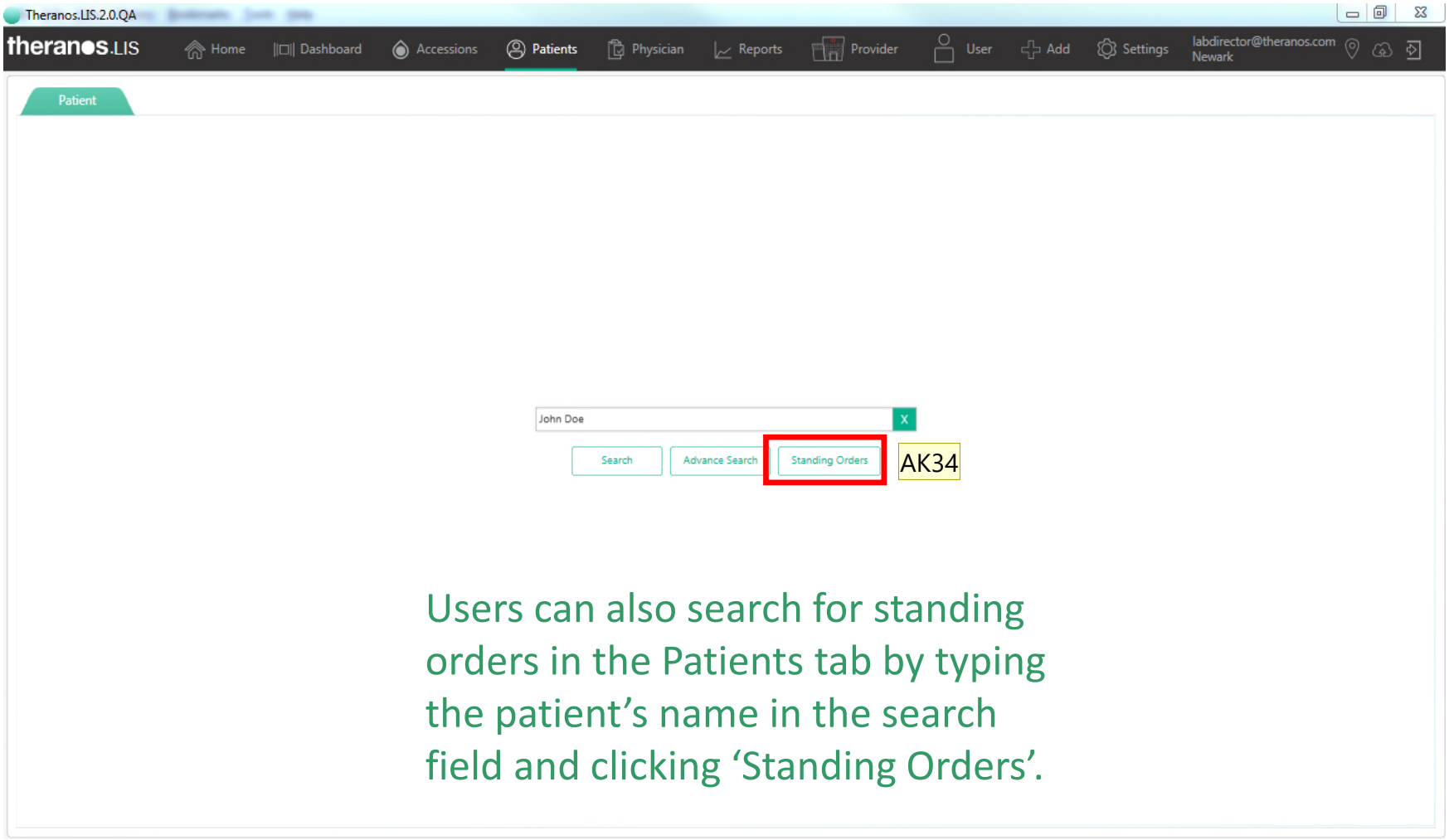
Searching for Patients



Or by Clinician information:

- Clinician Name
- Clinician Provider
- Clinician Location

Searching for Standing Orders



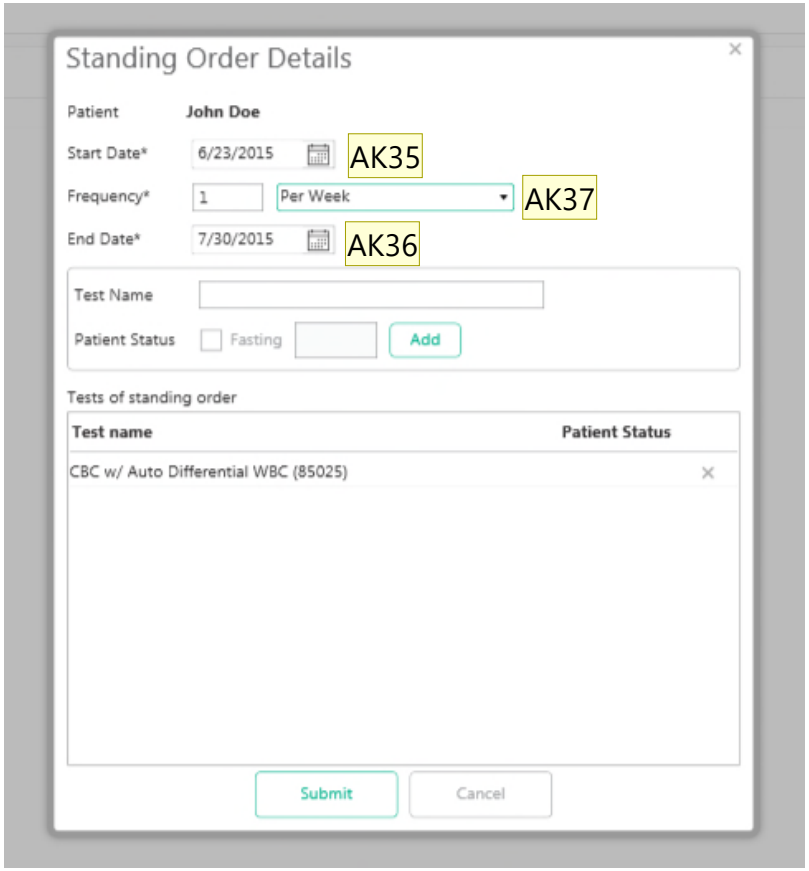
Users can also search for standing orders in the Patients tab by typing the patient's name in the search field and clicking 'Standing Orders'.

Slide 65

AK34 when physician's want the patient to havbe the same tests run on a continuous basis, provide the frequency and end date

Anam Khan, 6/24/2015

Editing Standing Orders



The Standing Order Details screen shows the start and end dates, the frequency, and the tests ordered for each standing order linked to a patient profile. Users are also able to edit the standing order on this screen.

Slide 66

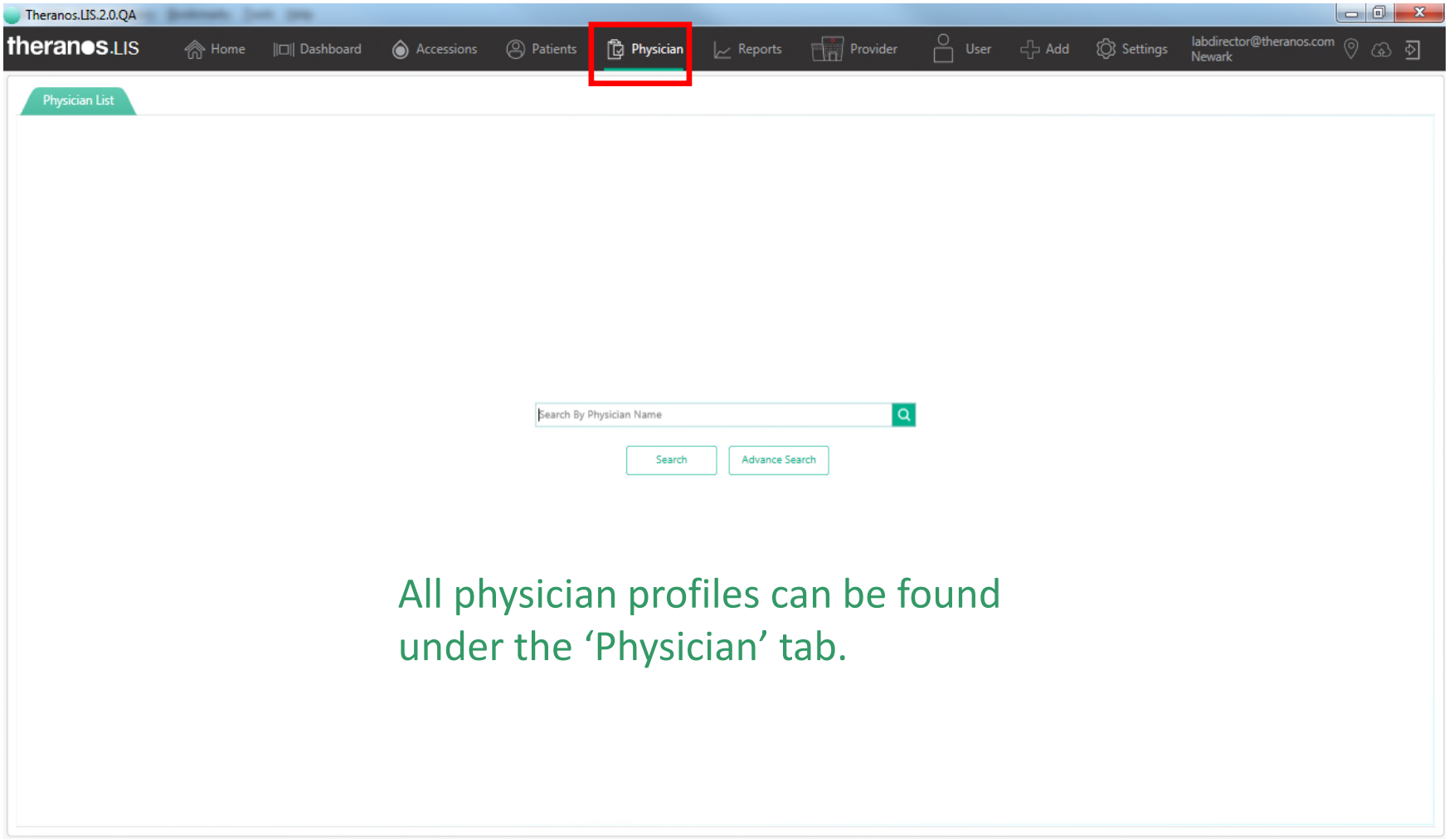
AK35 when the SO begins
Anam Khan, 6/24/2015

AK36 When the SO expires
Anam Khan, 6/24/2015

AK37 how often the test should be done
Anam Khan, 6/24/2015

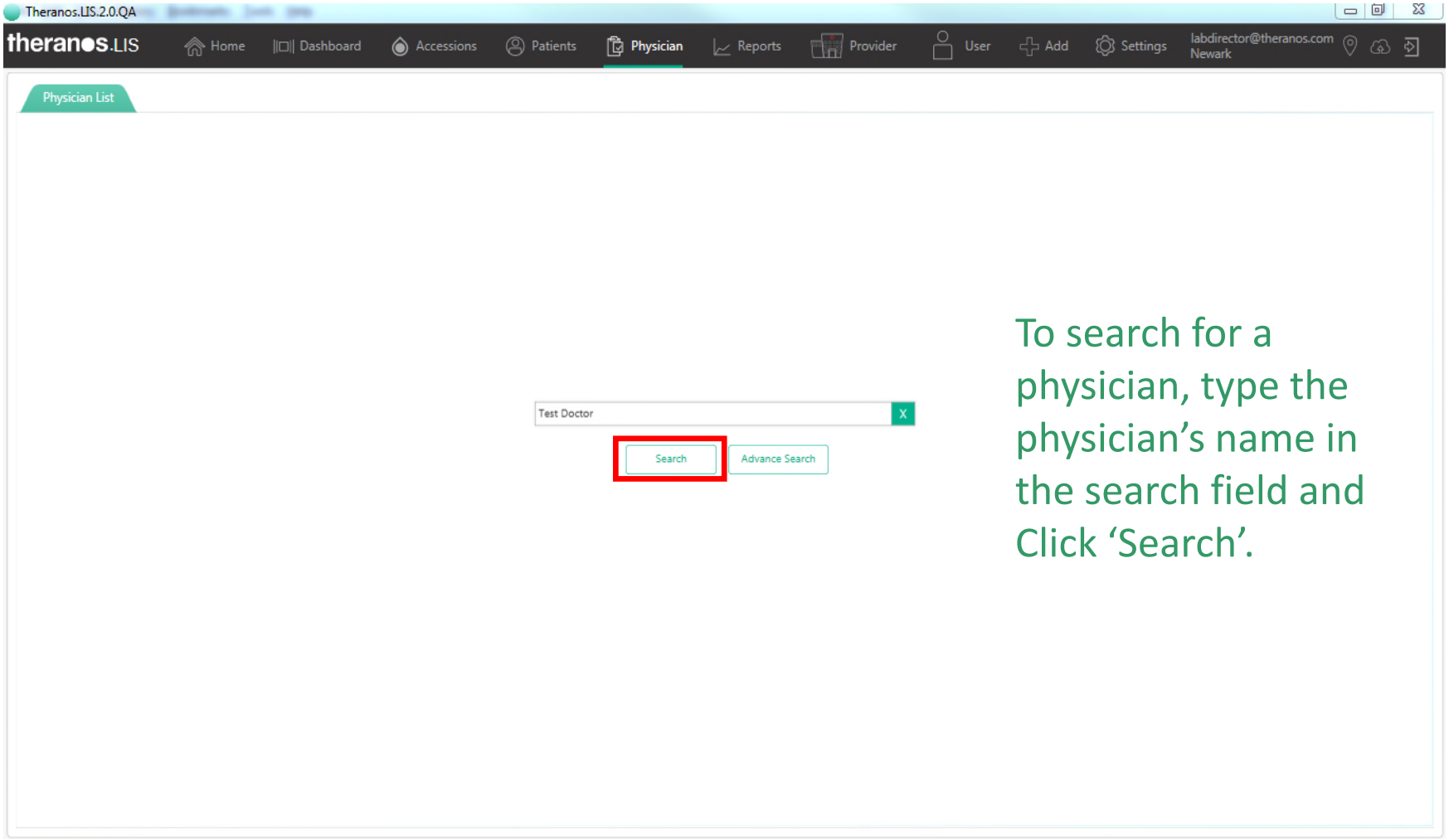
Physician Tab

Searching for Physicians



All physician profiles can be found under the 'Physician' tab.

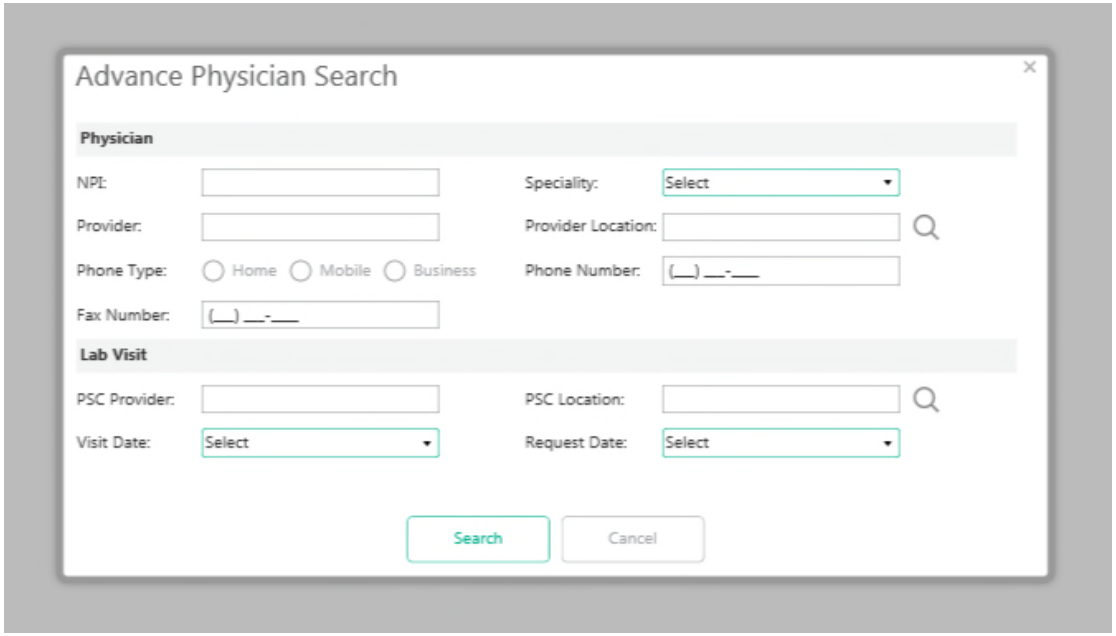
Searching for Physicians



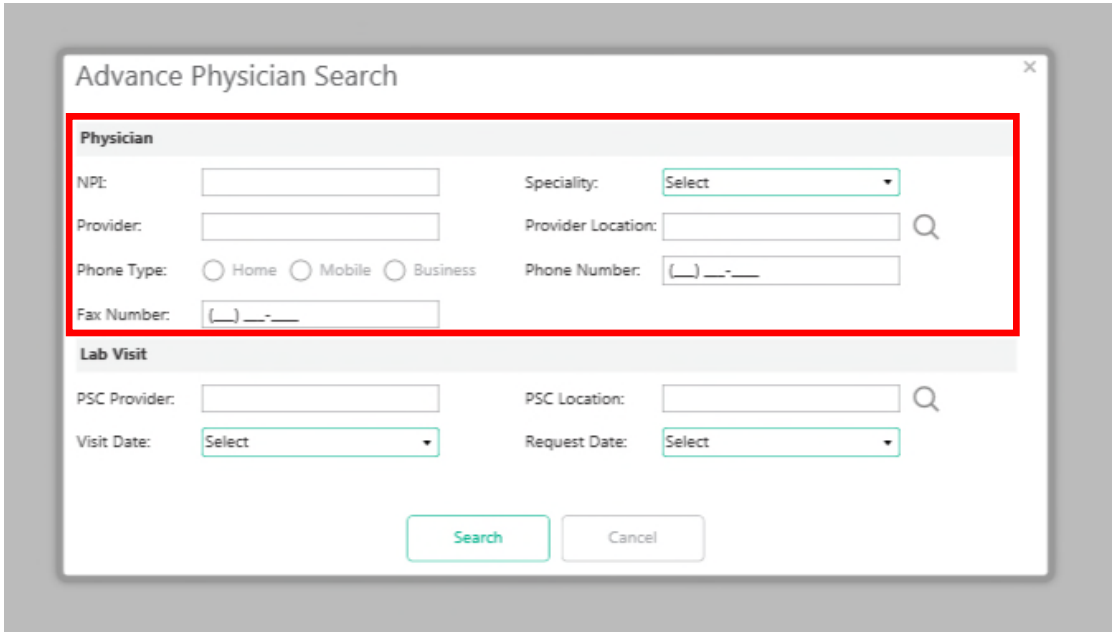
To search for a physician, type the physician's name in the search field and Click 'Search'.

Searching for Physicians

Clicking ‘Advanced Search’ allows the user to search for physician’s with specific parameters.



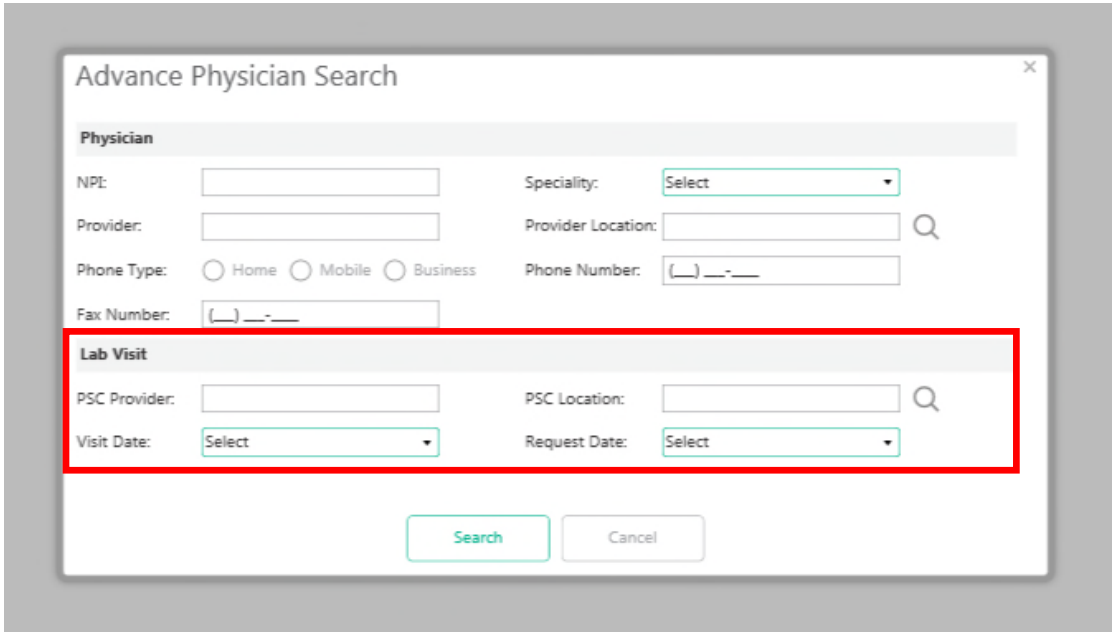
Searching for Physicians



Users can search for physician profiles by physician information:

- NPI
- Specialty
- Provider
- Provider Location
- Phone Type and #
- Fax #

Searching for Physicians

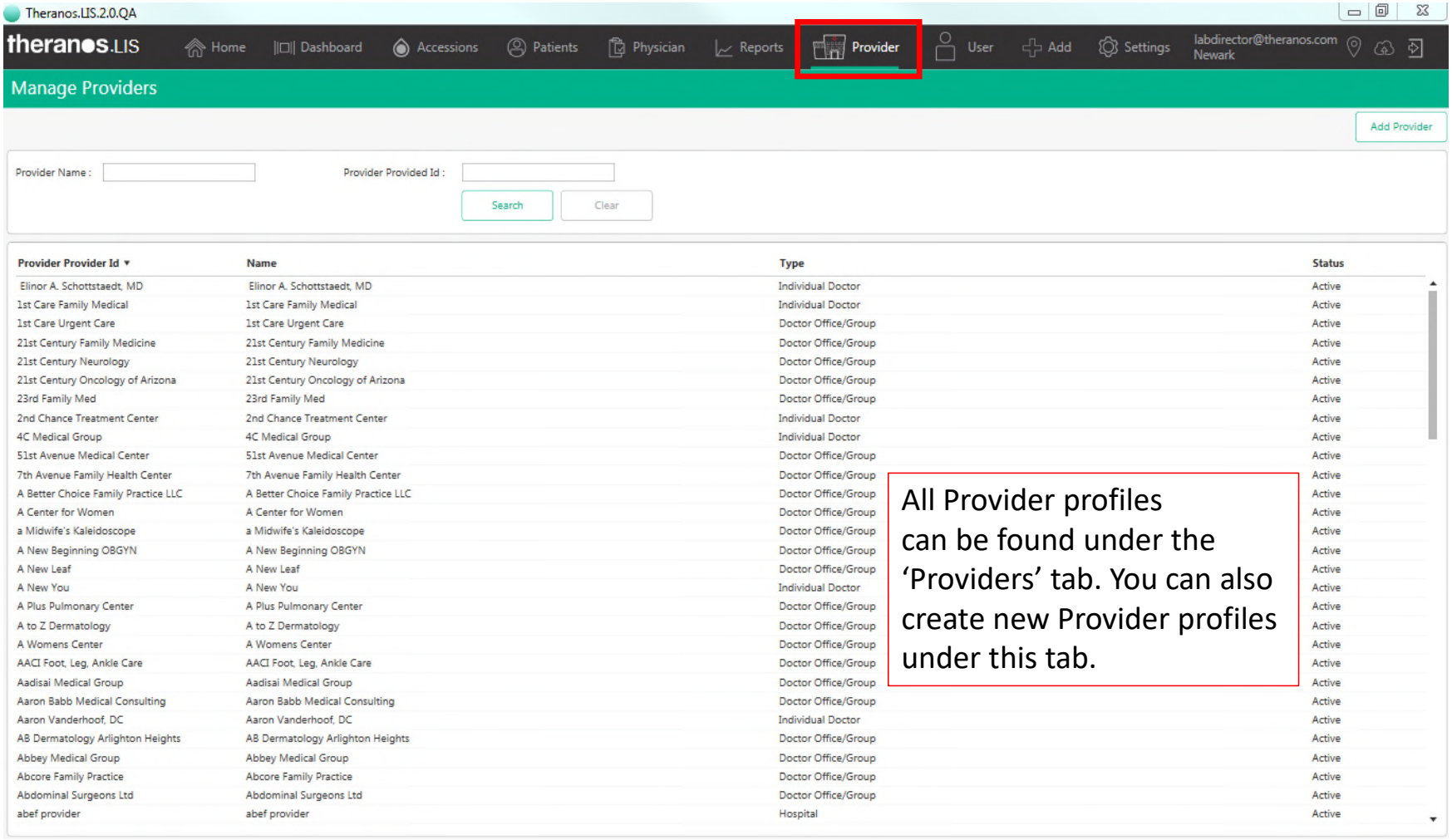


And by lab visit information:

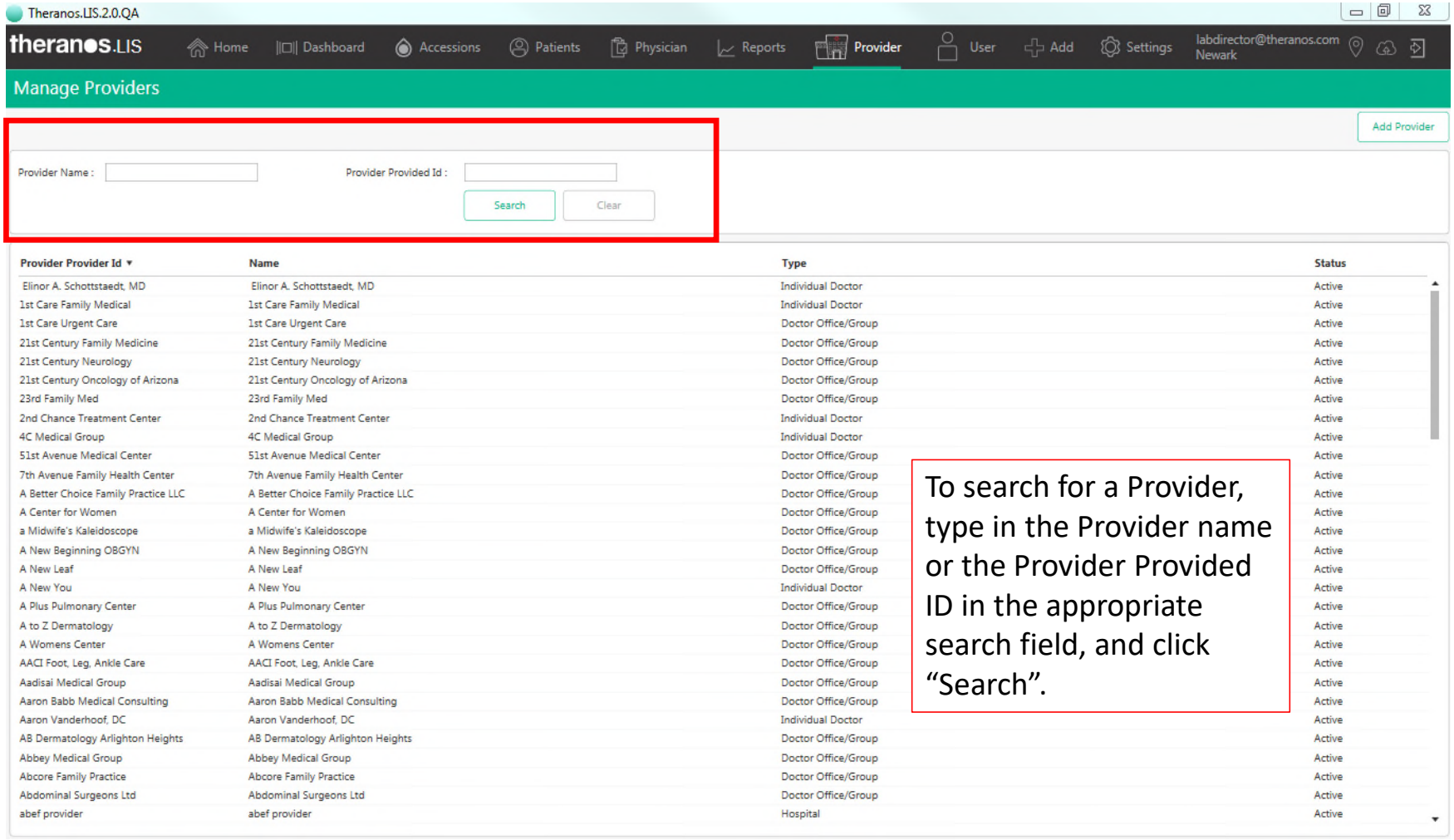
- PSC Provider
- PSC Location
- Visit Date
- Request Date

Provider Tab

Searching for Providers

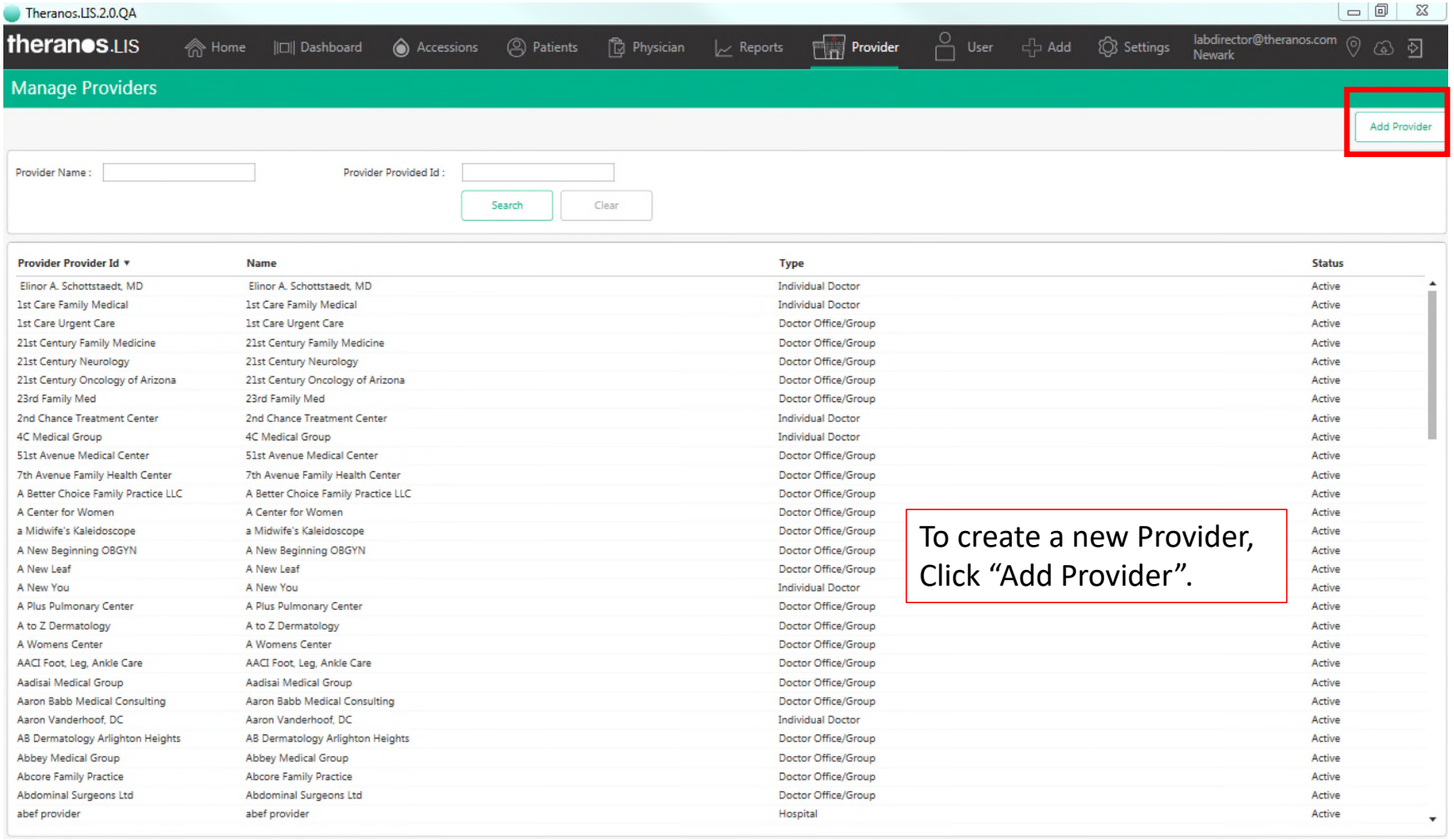


Searching for Providers

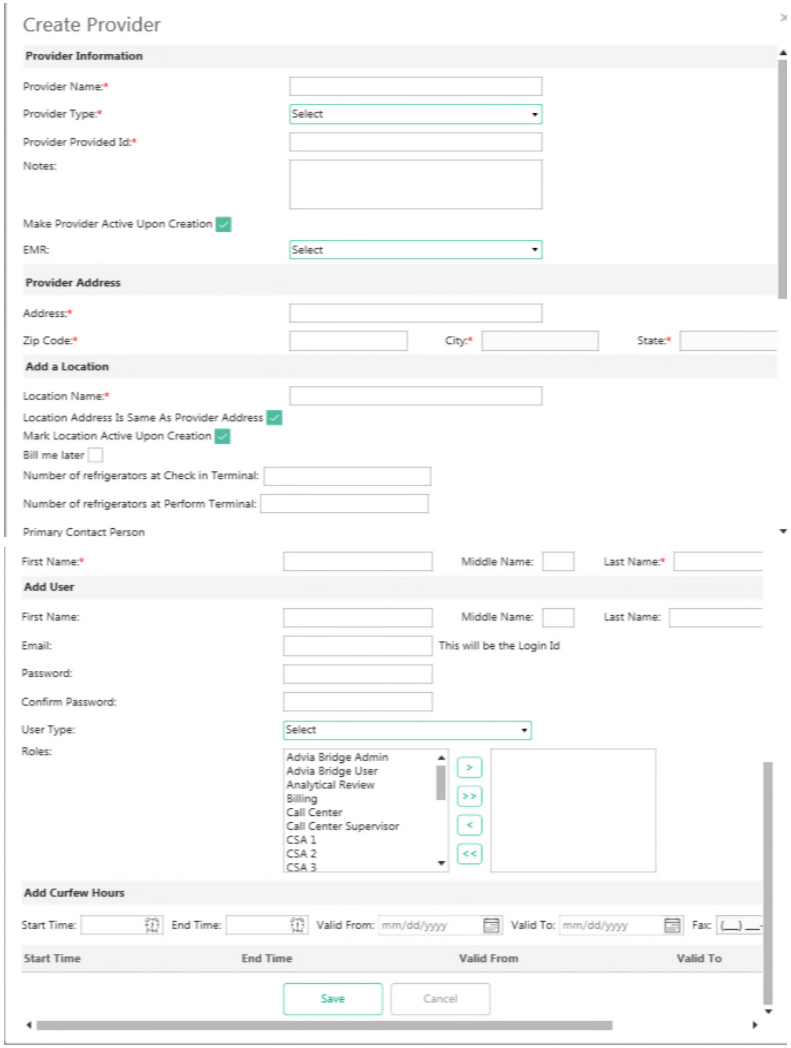


To search for a Provider, type in the Provider name or the Provider Provided ID in the appropriate search field, and click "Search".

Adding New Providers



Adding New Providers



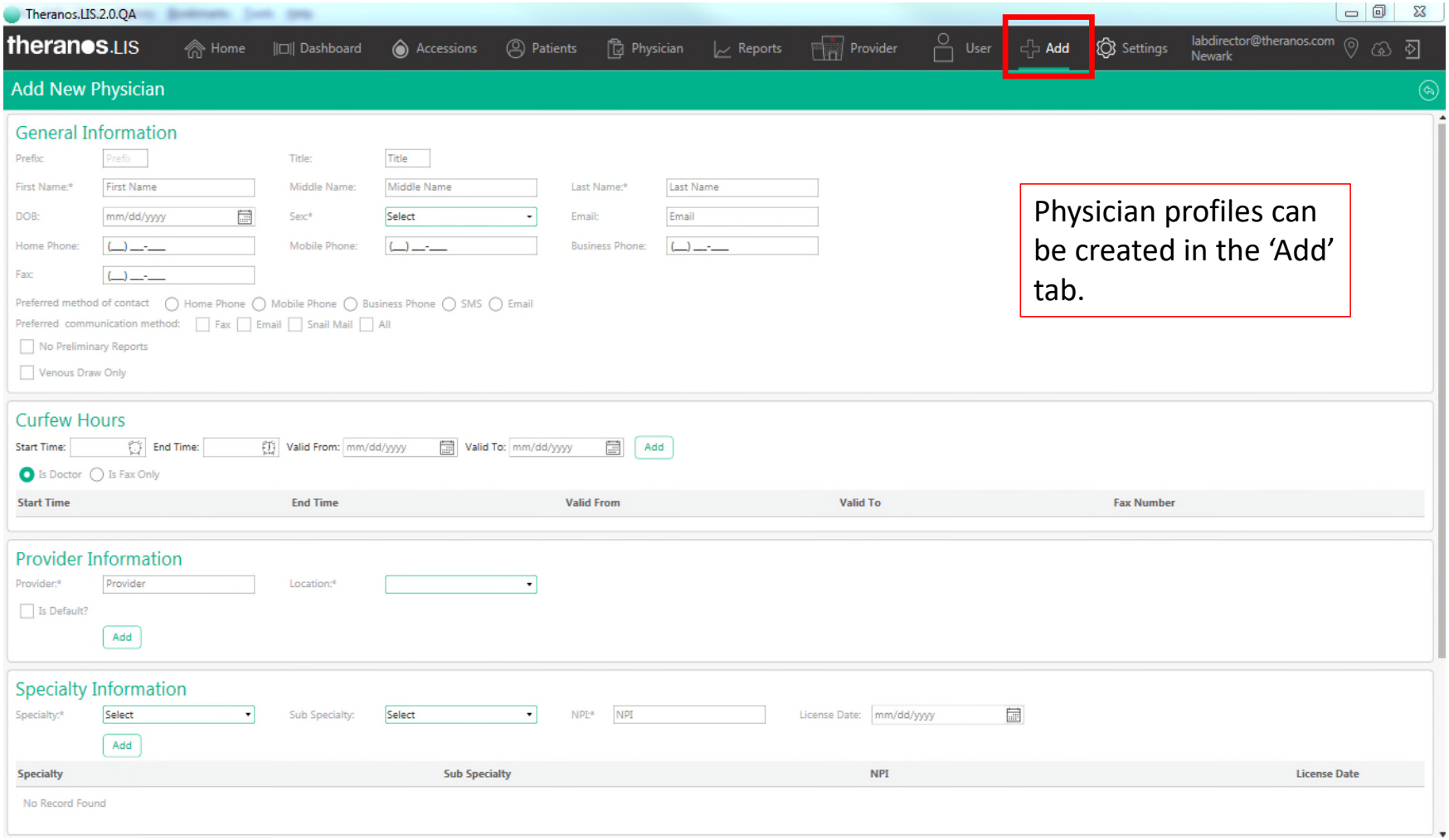
To Create a Provider:

1. Enter in Provider Name
2. Choose Provider Type from the drop-down menu
3. Enter in Provider Provided ID (should be the same as the Provider name)
3. Enter in the Provider address
4. Enter in the Location Name
5. Enter in the name of a primary contact person (this can be the name of the physician associated with this provider)
6. Click “Save”.

Add Tab

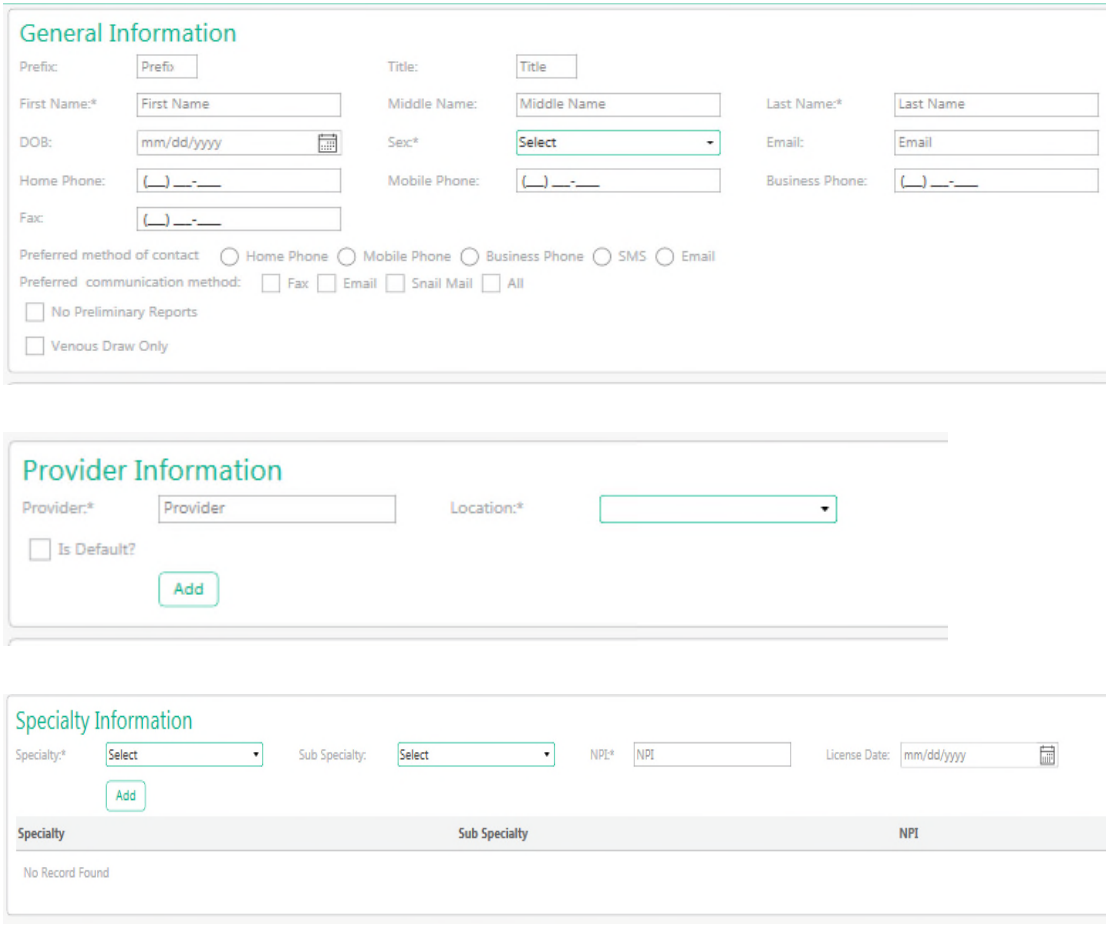
Creating Physician Profiles

Creating New Physician Profiles



Physician profiles can be created in the 'Add' tab.

Creating New Physician Profiles



Creating a Physician Profile:

1. General Information- Enter in the physician's name and contact info

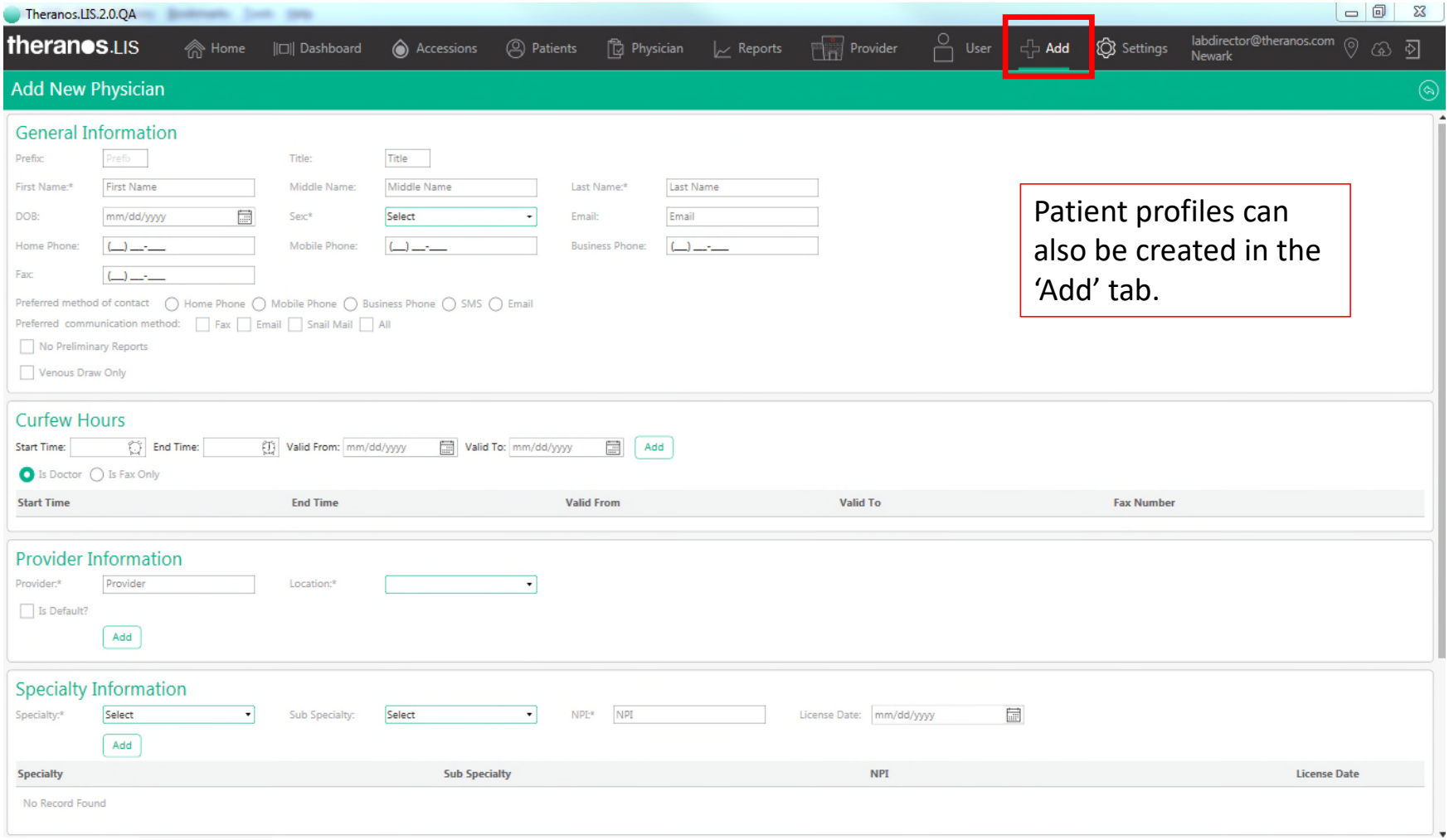
2. Provider Information- Select a Provider and Location. If this is the physician's primary location, check 'Is Default?', and then click 'Add'.

3. Specialty Information- Choose a Specialty from the drop down menu and enter in the physician's 10 digit NPI #, then Click 'Add'.

4. Click 'Save'

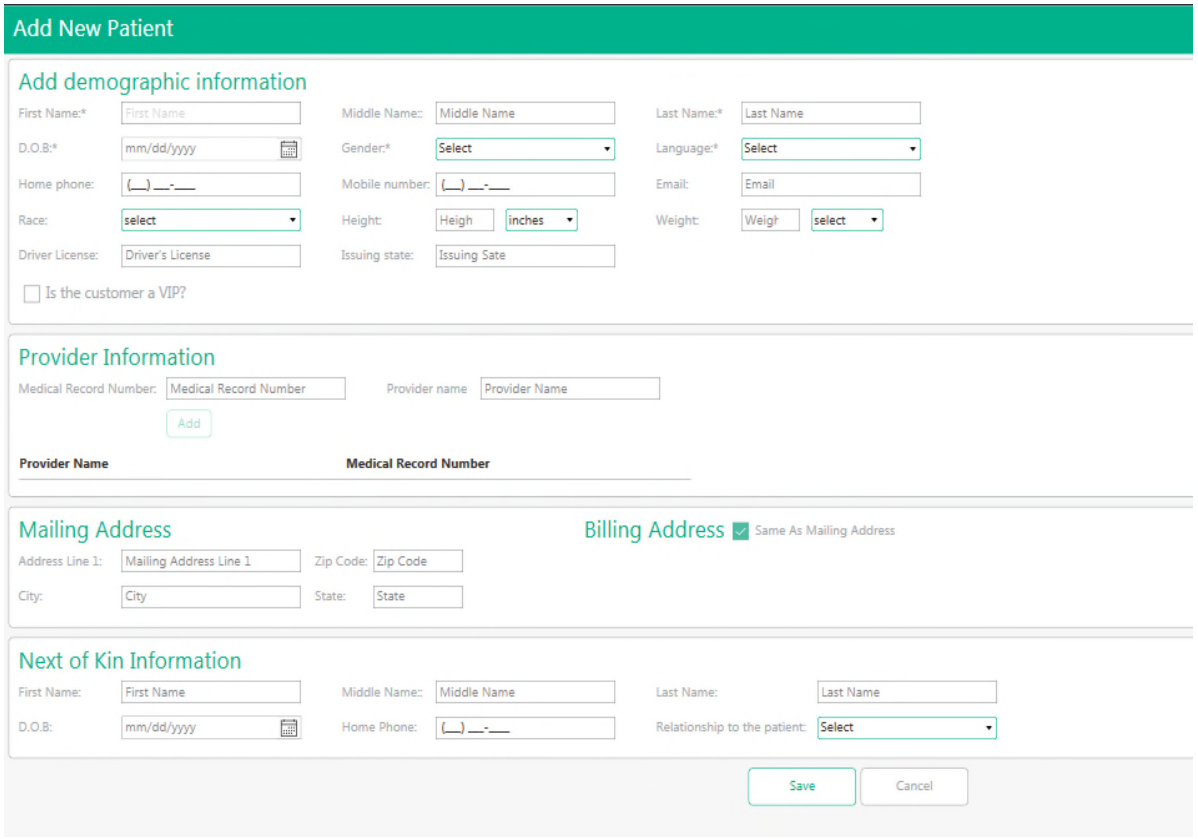
Creating Patient Profiles

Creating New Patient Profiles



Patient profiles can also be created in the 'Add' tab.

Creating New Patient Profiles



Creating a Patient Profile:

1. Demographic Information: Enter in the patient's name and contact info

2. Provider Information: Can enter in a MRN link the patient to an existing Provider

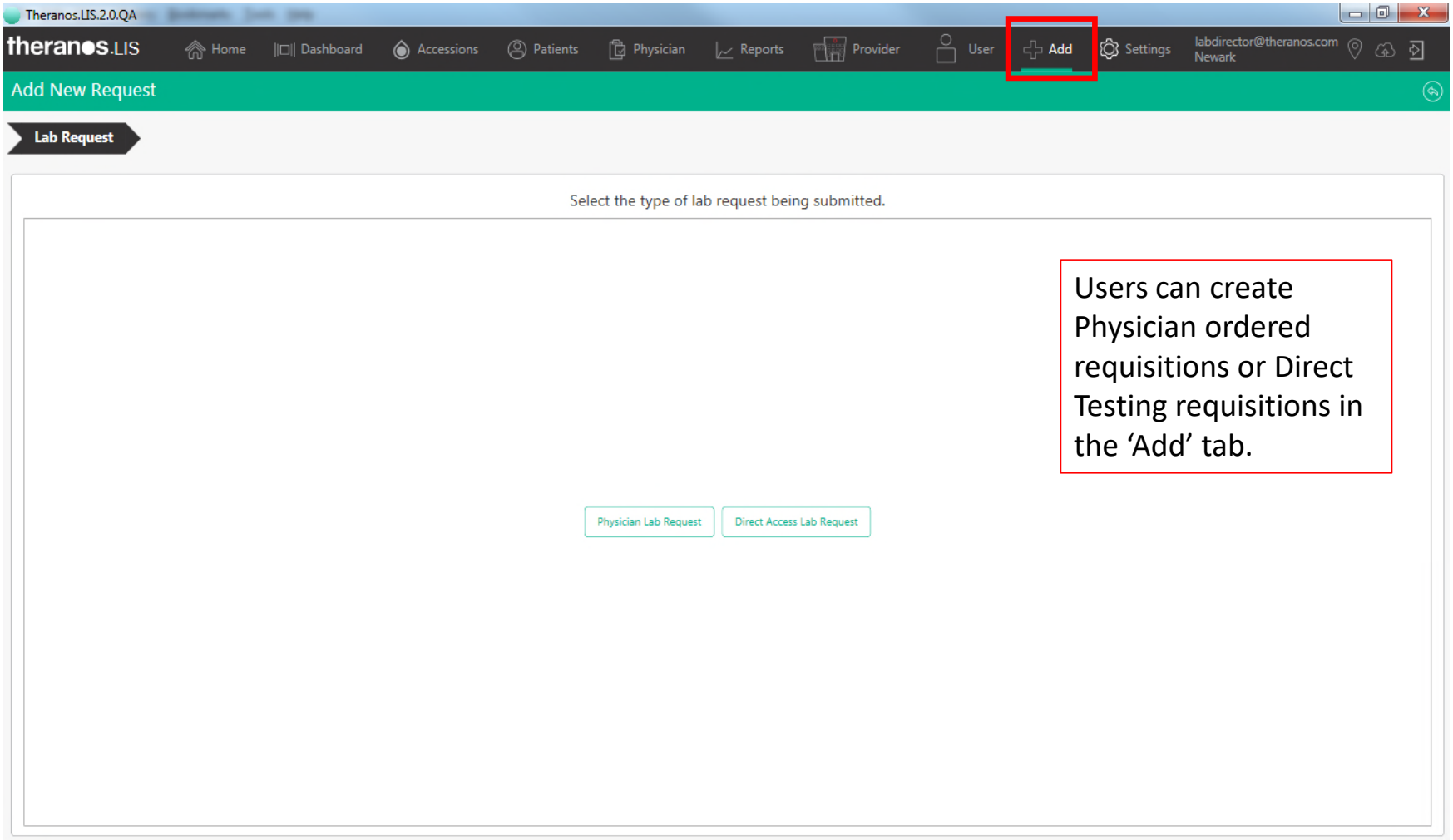
3. Mailing Address: Enter in the patient's mailing address. The city and state fields will auto-populate when a zip code is entered

4. Next of Kin Information: Enter in the Next of Kin information. *Required for Direct Testing is patient <18

5. Click 'Save'

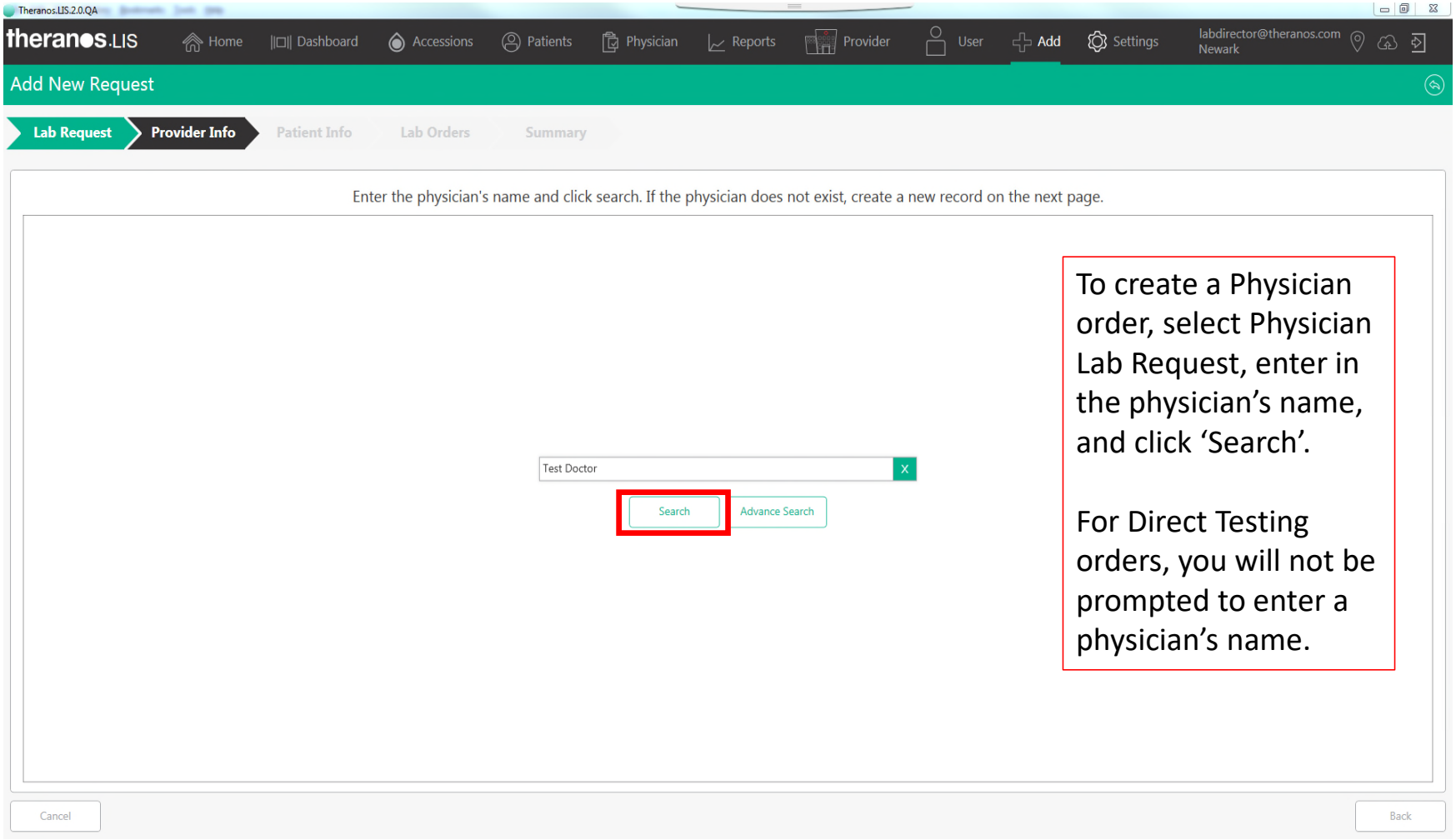
Creating Requisitions

Creating Requisitions



Users can create Physician ordered requisitions or Direct Testing requisitions in the 'Add' tab.

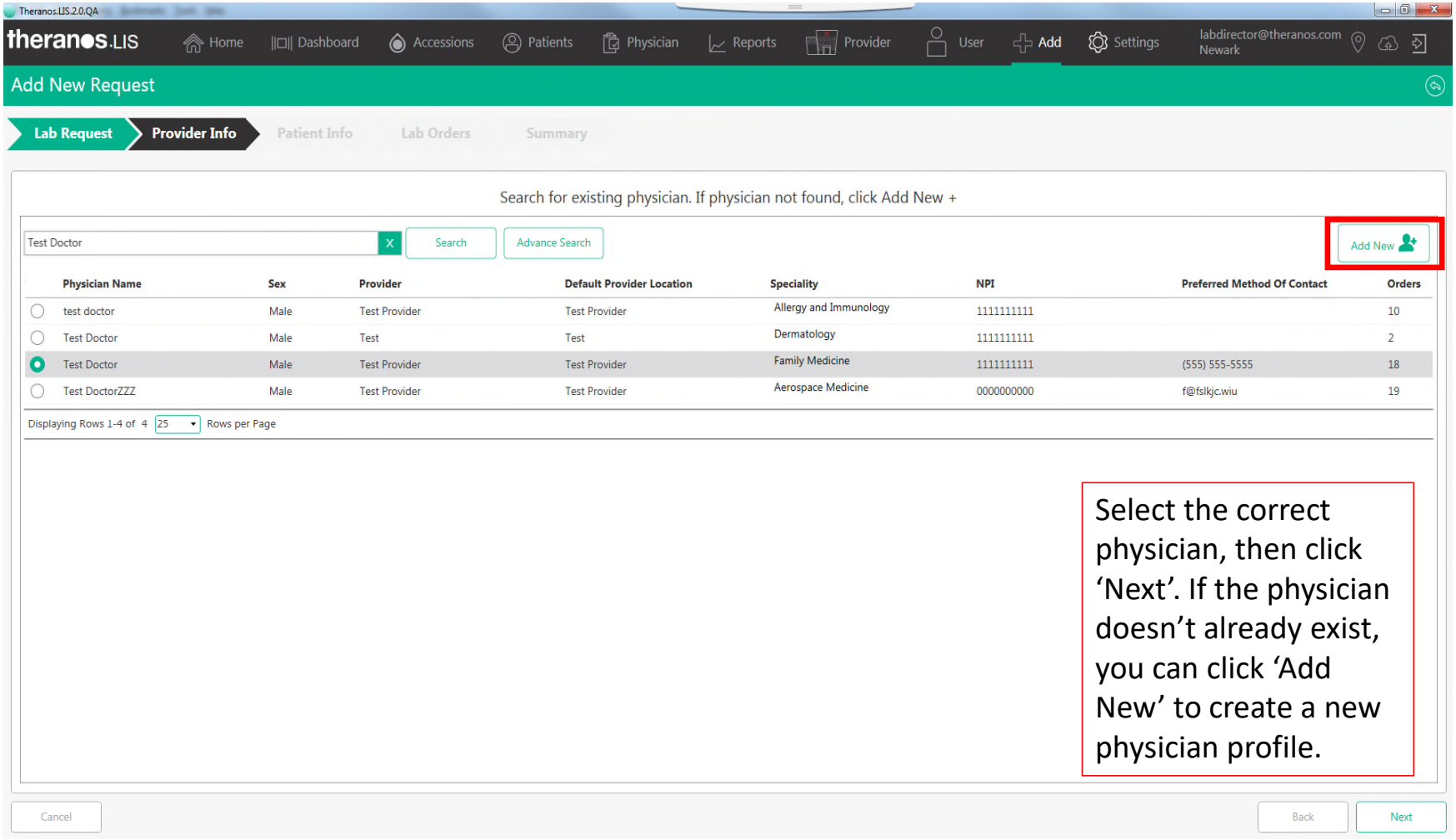
Creating Requisitions- Adding Physician



To create a Physician order, select Physician Lab Request, enter in the physician's name, and click 'Search'.

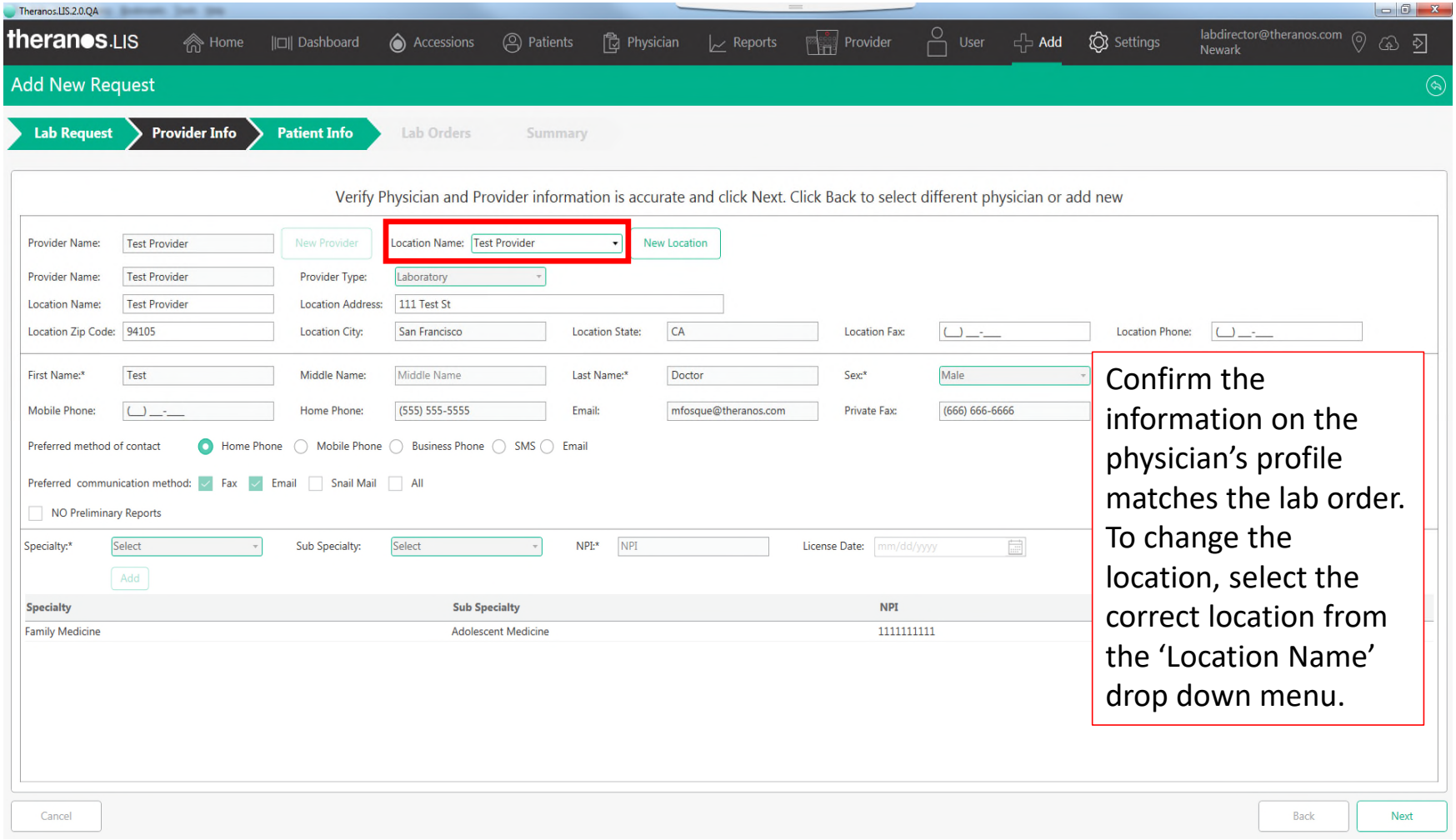
For Direct Testing orders, you will not be prompted to enter a physician's name.

Creating Requisitions- Adding Physician



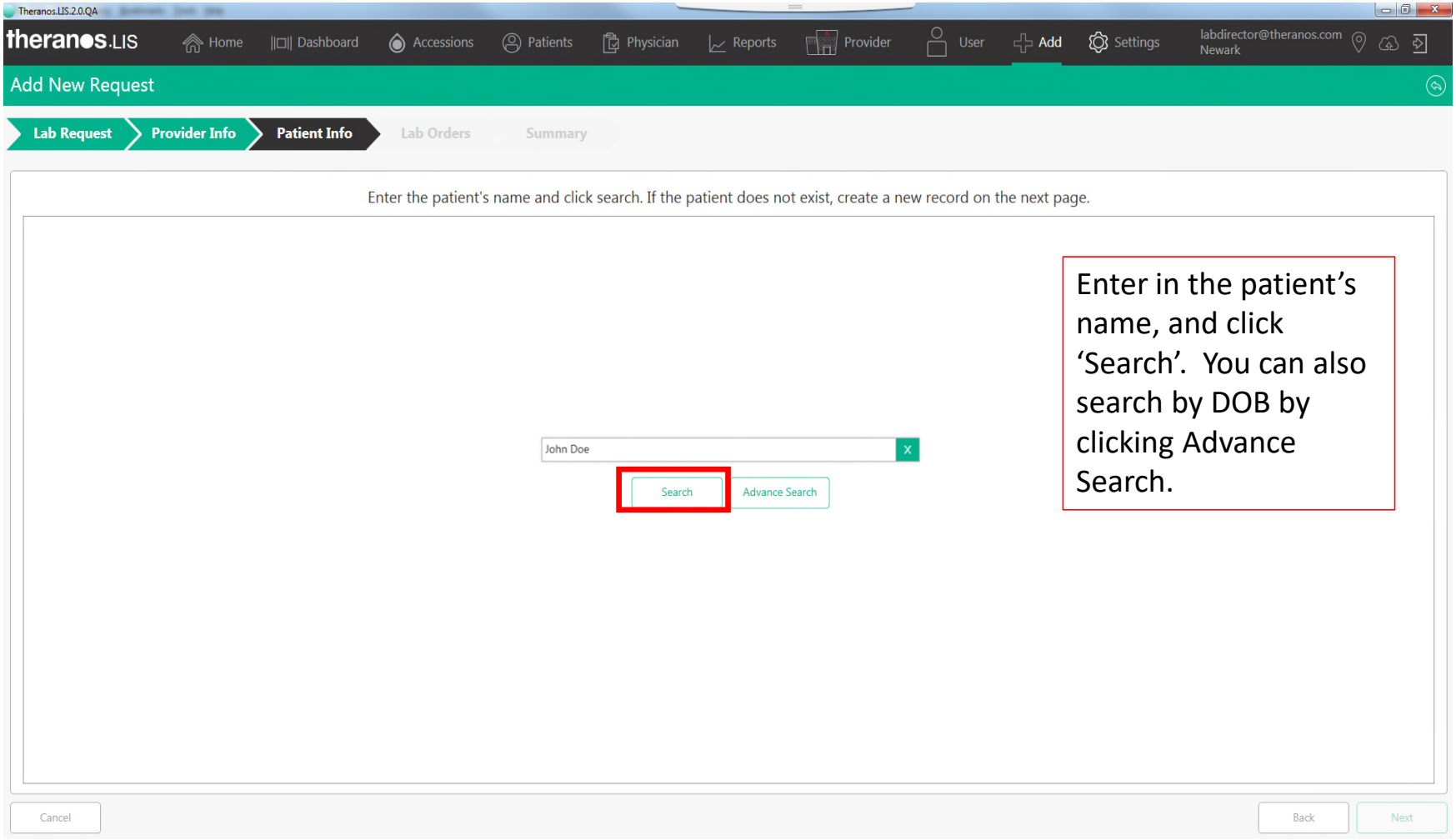
Select the correct physician, then click 'Next'. If the physician doesn't already exist, you can click 'Add New' to create a new physician profile.

Creating Requisitions- Adding Physician

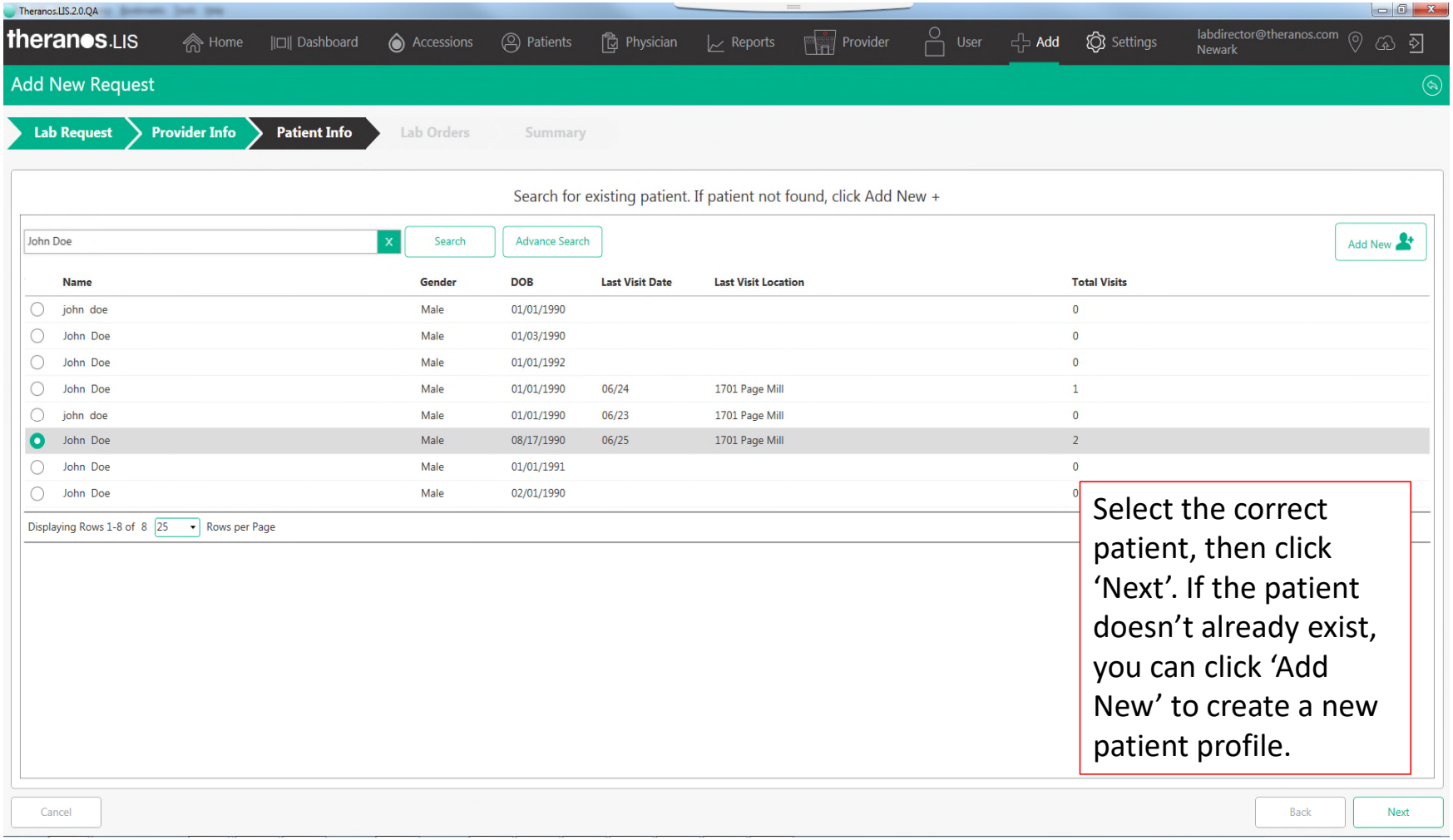


Confirm the information on the physician's profile matches the lab order. To change the location, select the correct location from the 'Location Name' drop down menu.

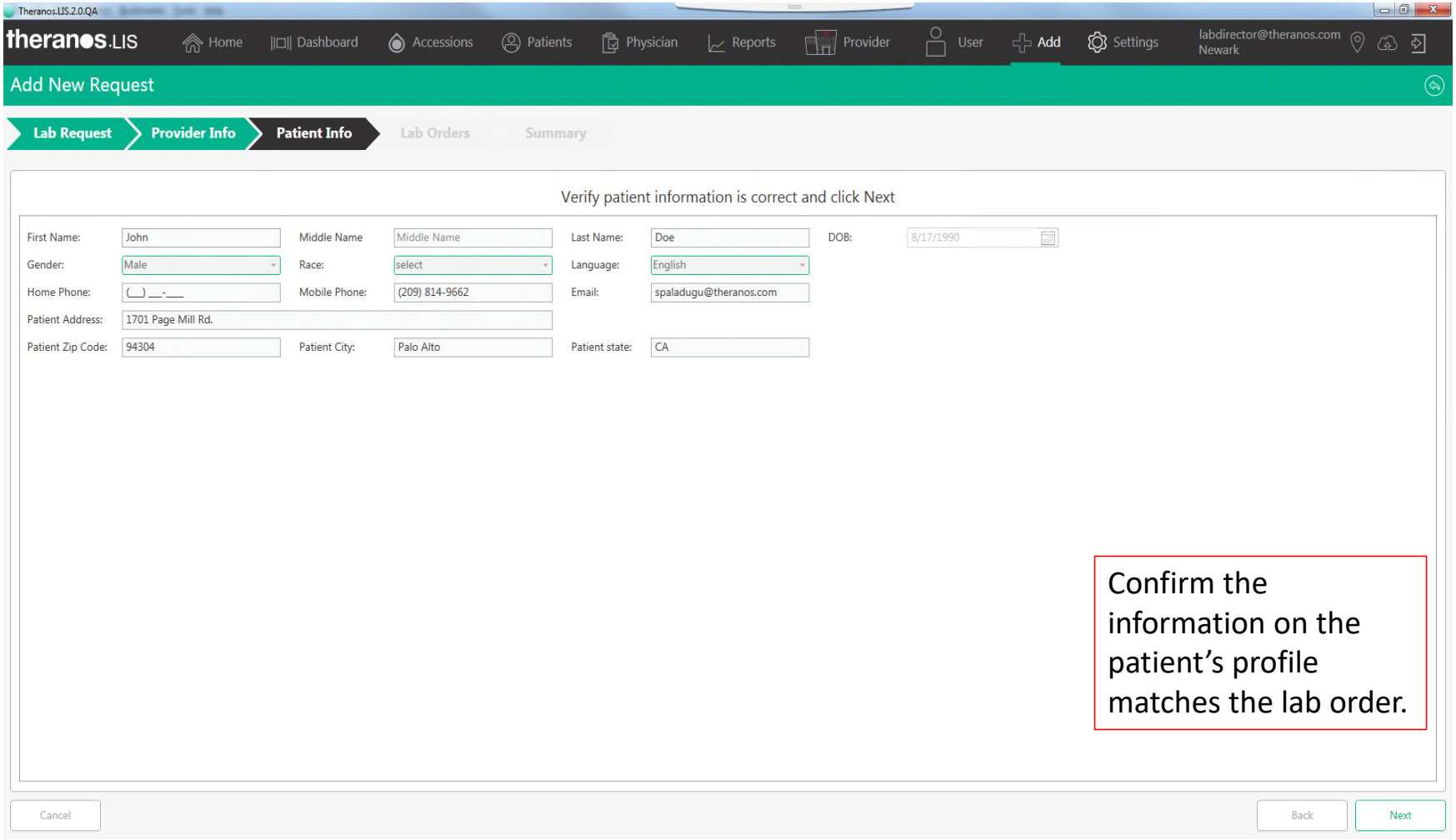
Creating Requisitions- Adding Patient



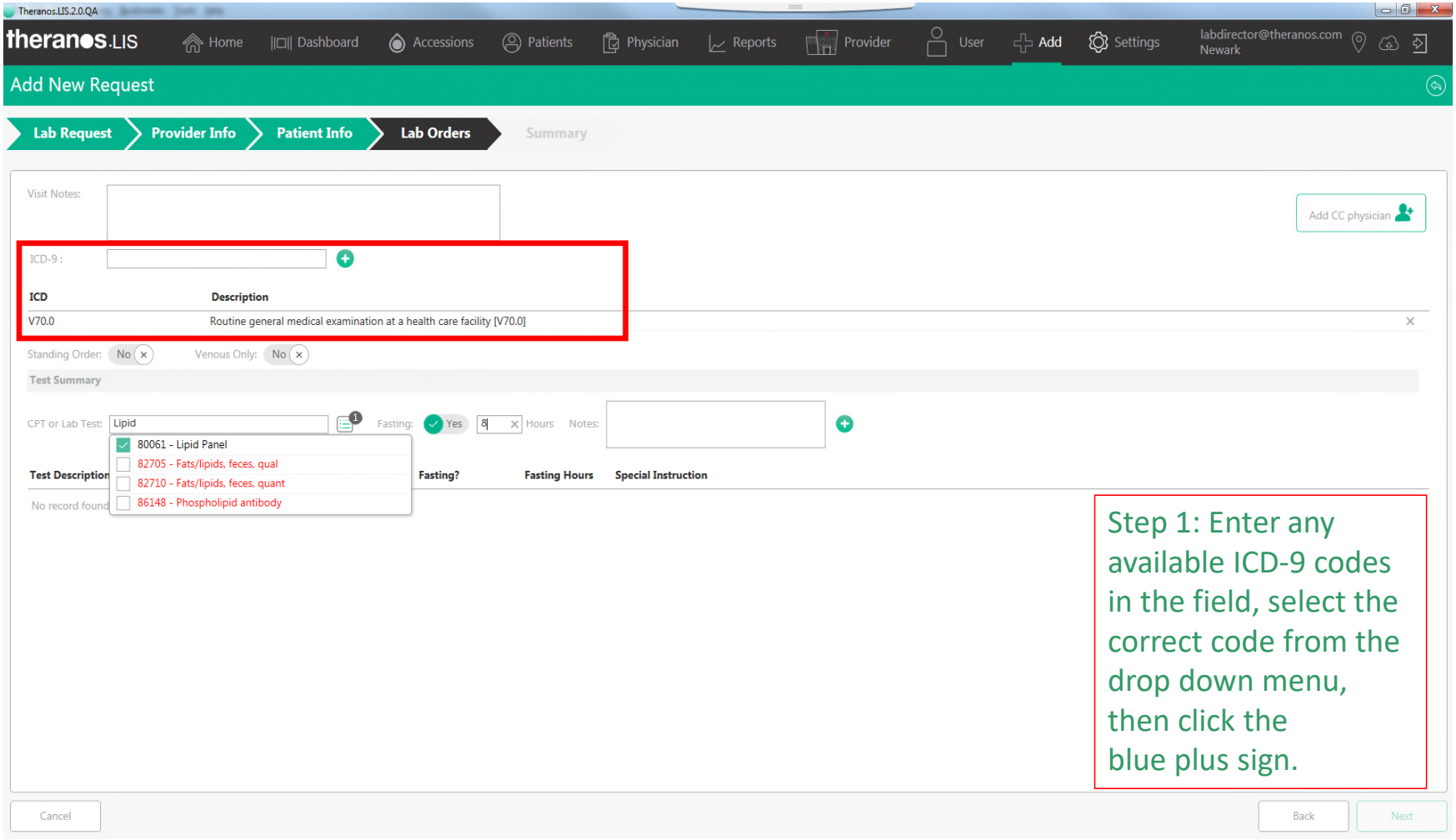
Creating Requisitions- Adding Patient



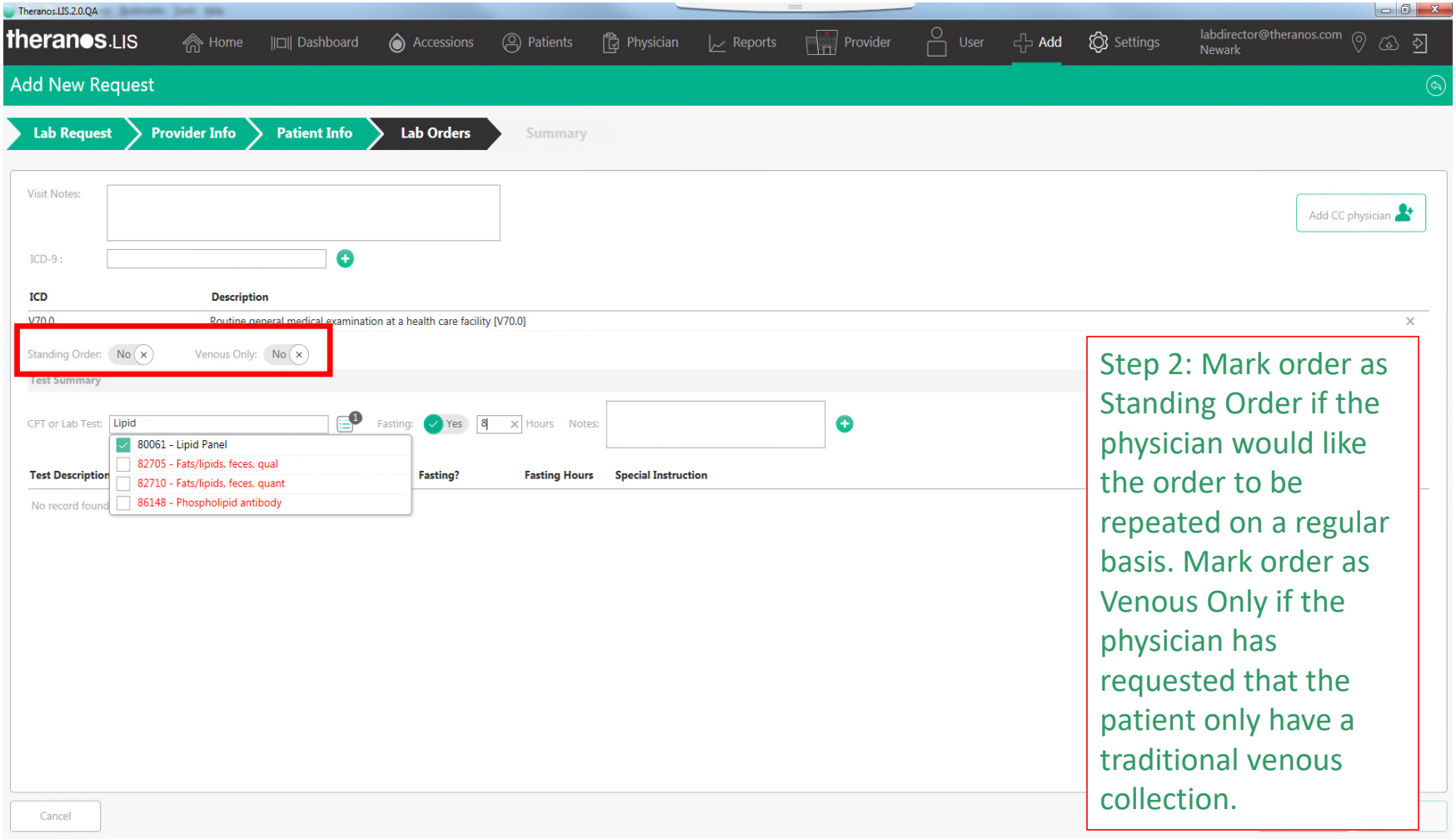
Creating Requisitions- Adding Patient



Creating Requisitions- Adding ICD 9/10 Codes

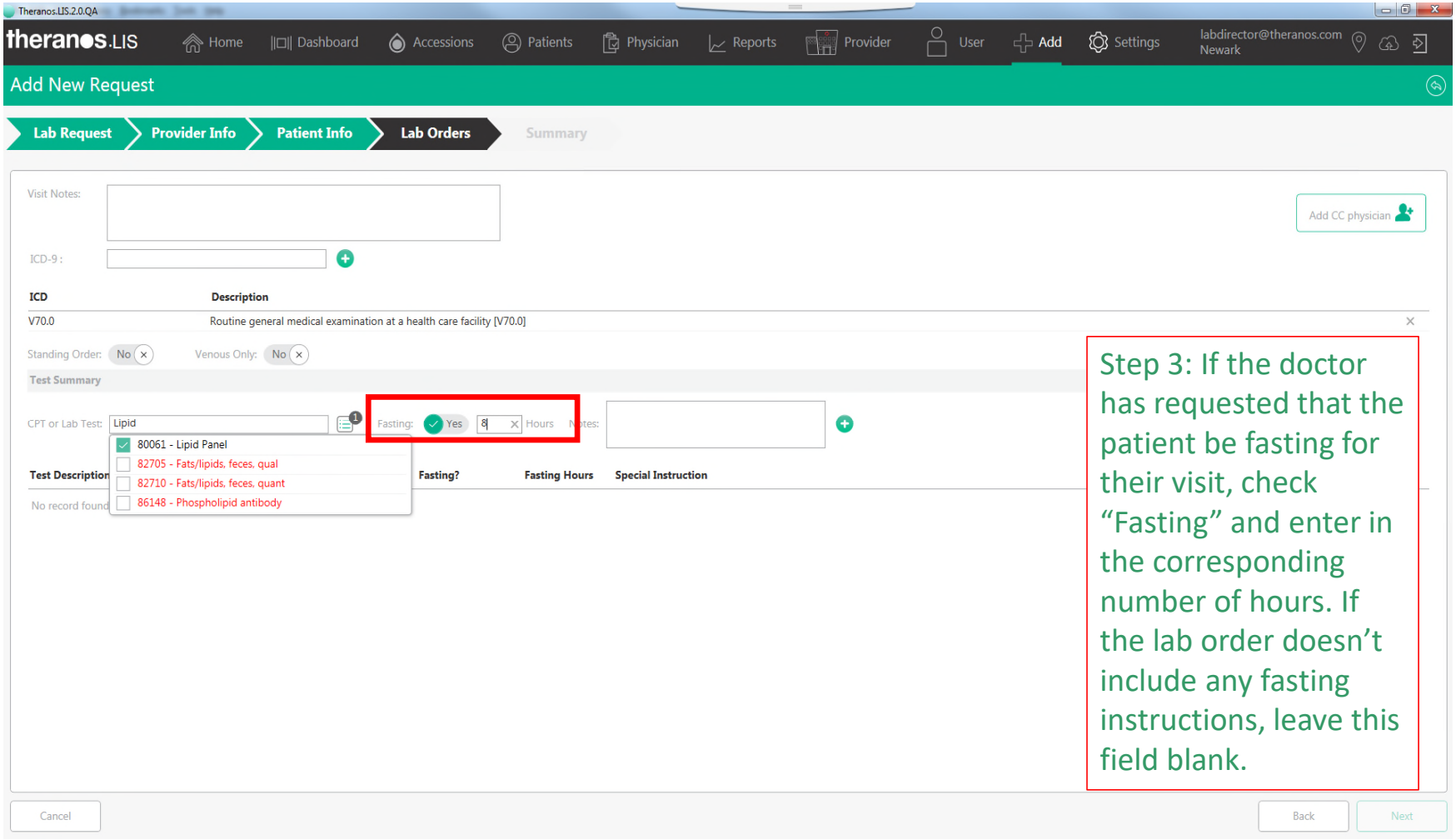


Creating Requisitions- Standing Orders, Venous Preference



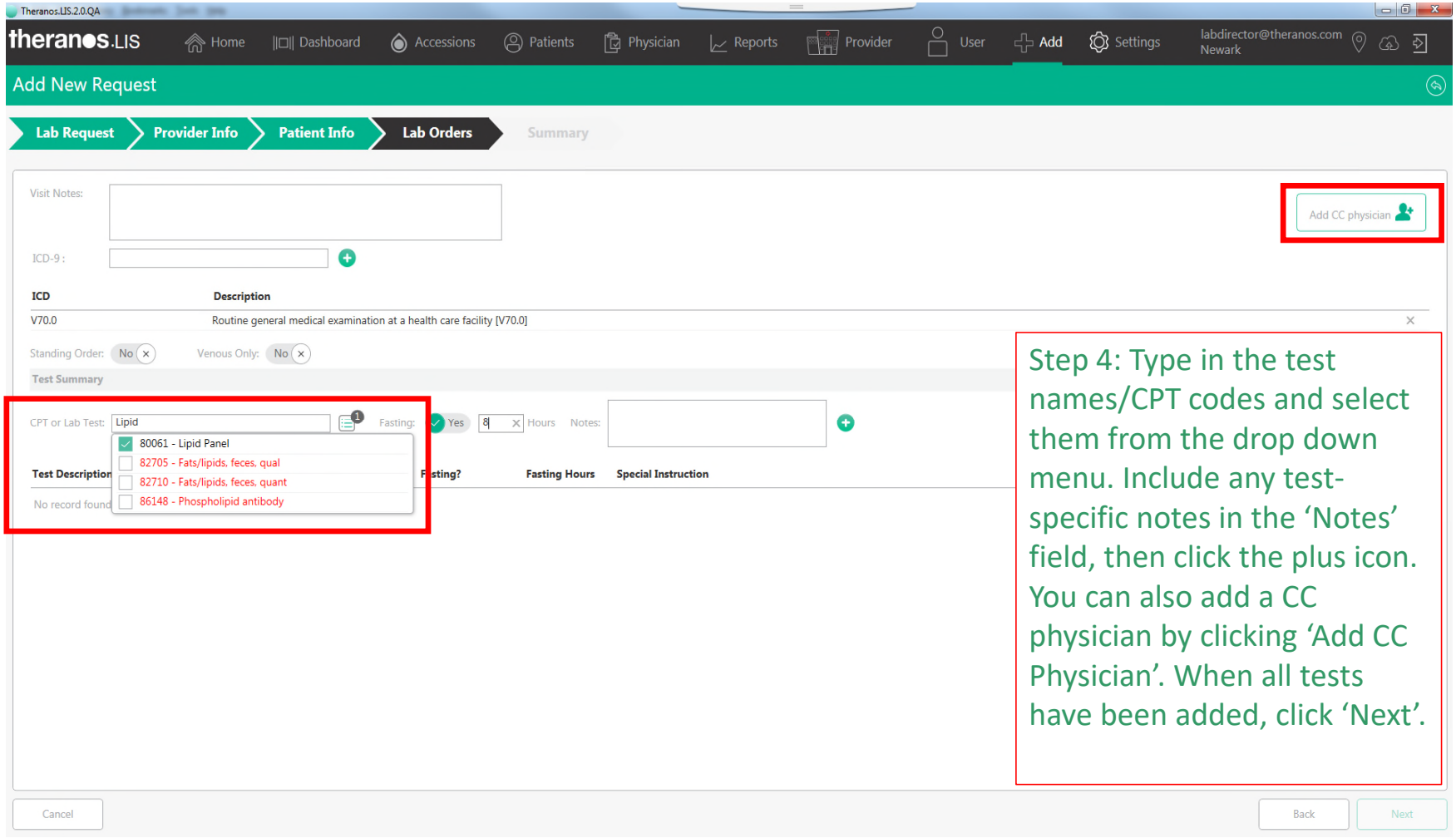
Step 2: Mark order as Standing Order if the physician would like the order to be repeated on a regular basis. Mark order as Venous Only if the physician has requested that the patient only have a traditional venous collection.

Creating Requisitions- Fasting



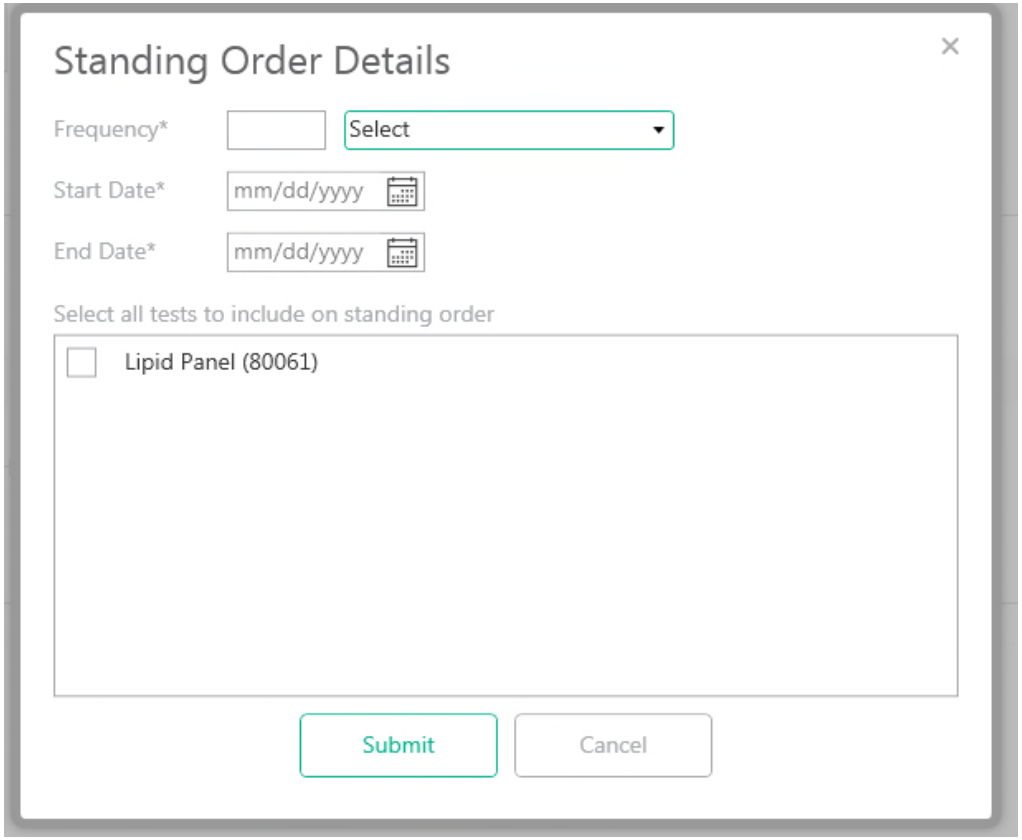
Step 3: If the doctor has requested that the patient be fasting for their visit, check "Fasting" and enter in the corresponding number of hours. If the lab order doesn't include any fasting instructions, leave this field blank.

Creating Requisitions- Adding Tests, Adding Copy-to Physician



Step 4: Type in the test names/CPT codes and select them from the drop down menu. Include any test-specific notes in the 'Notes' field, then click the plus icon. You can also add a CC physician by clicking 'Add CC Physician'. When all tests have been added, click 'Next'.

Creating Requisitions- Standing Order

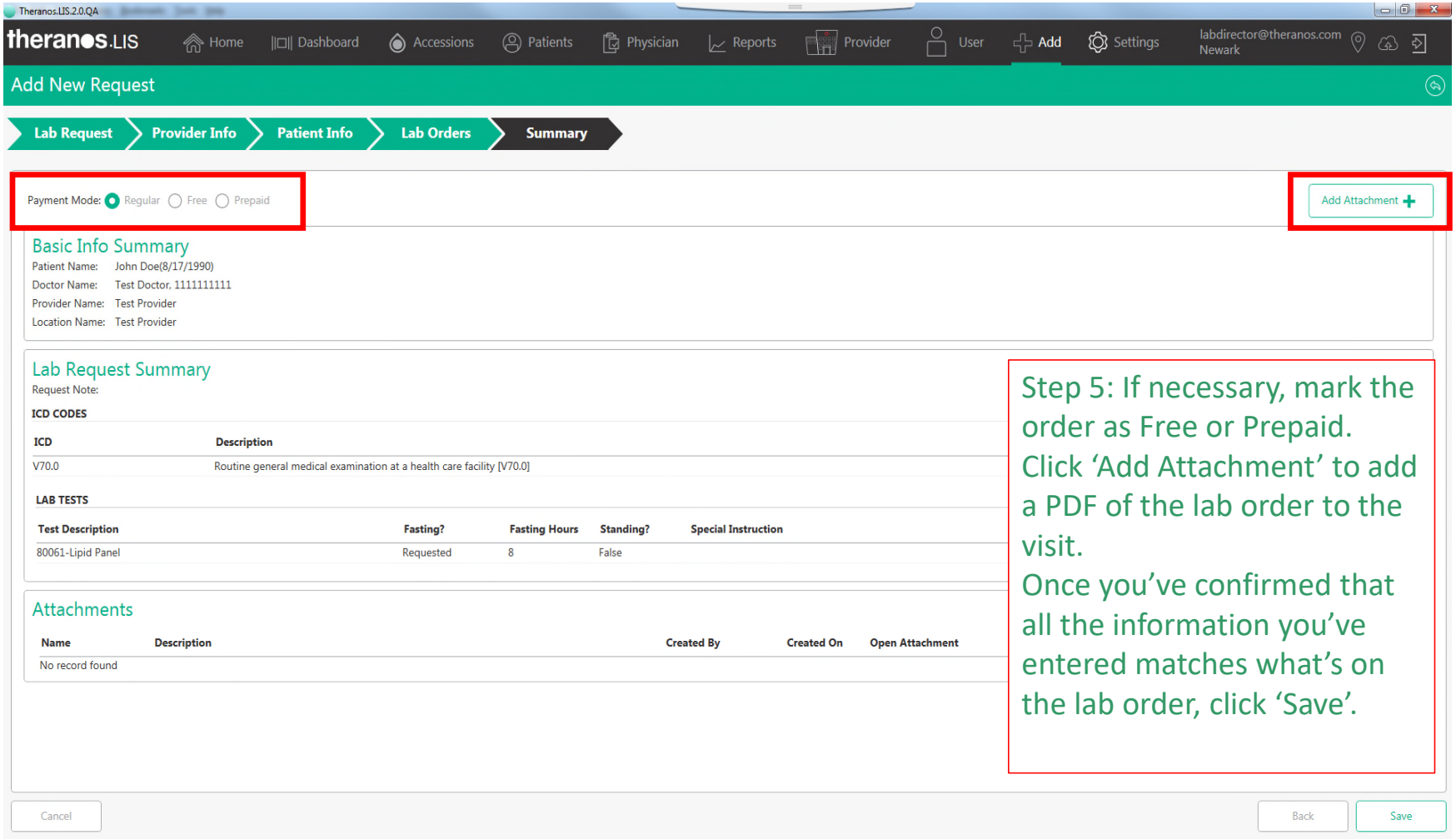


If you mark the order as a standing order, you'll see this pop up.

1. Designate the frequency of the order
2. Select a Start Date and an End Date
3. Select the tests that should be included on the standing order.
4. Click 'Submit'

Note- All tests on the Theranos test menu are eligible to be a standing order.

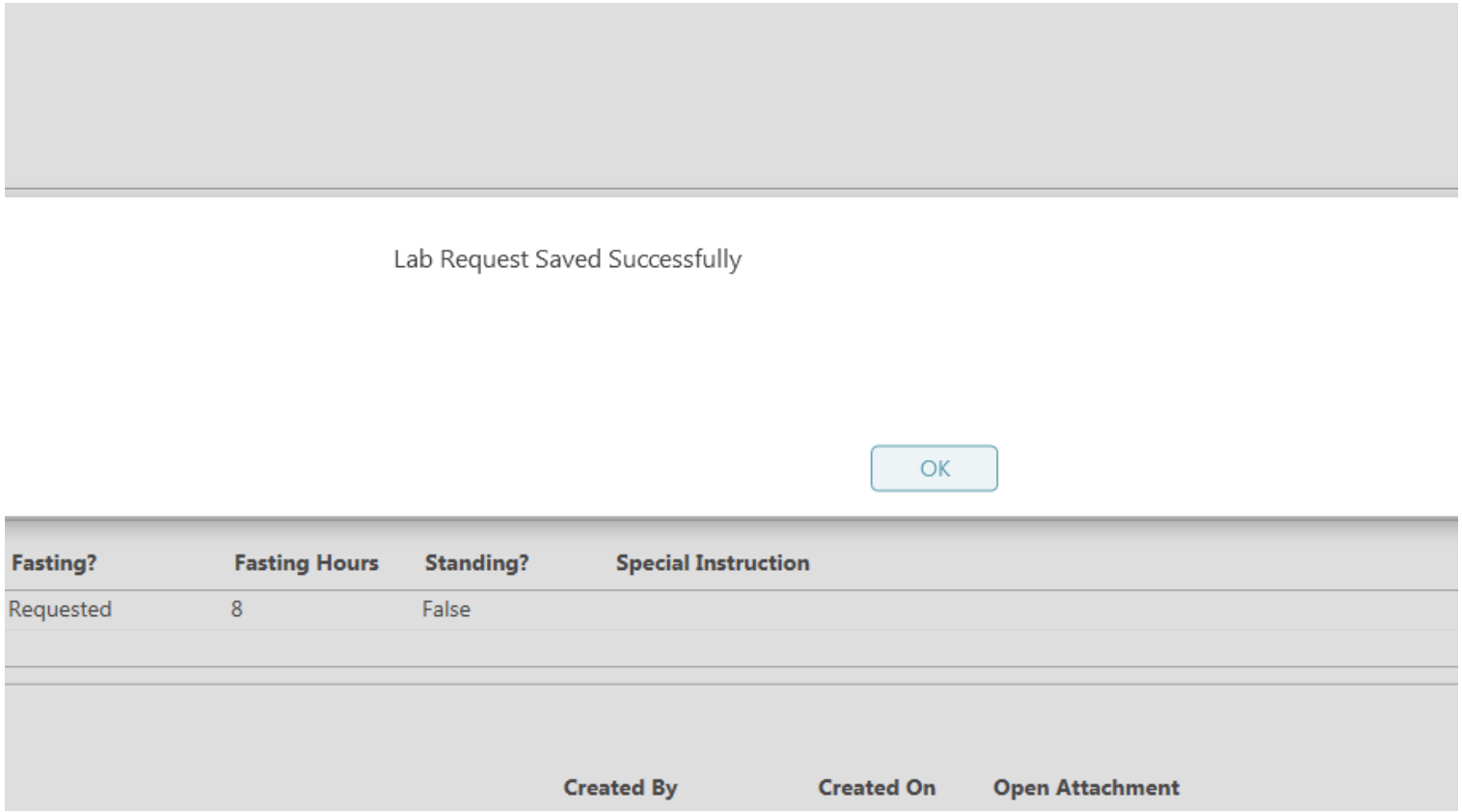
Creating Requisitions- Payment Mode, Add Attachments



Step 5: If necessary, mark the order as Free or Prepaid.
Click 'Add Attachment' to add a PDF of the lab order to the visit.
Once you've confirmed that all the information you've entered matches what's on the lab order, click 'Save'.

Creating Requisitions

You'll receive confirmation once the order has been created successfully.



REVISION HISTORY			
Revision Level	**Effective Date**	**Initiator**	**DCO Number**
A	10/20/2015	Anam Khan	DCO-00104
Section Number	**Description and Justification of Changes**		
All	Initial Release		

EXHIBIT 25

IN THE COURT OF CHANCERY OF THE STATE OF DELAWARE

PARTNER INVESTMENTS, L.P., a Delaware limited partnership, PFM HEALTHCARE MASTER FUND, L.P., a Cayman Islands limited partnership, and PFM HEALTHCARE PRINCIPALS FUND, L.P., a Delaware limited partnership,

Plaintiff,

vs. Case No. 12816-VCL

THERANOS, INC., a Delaware corporation, ELIZABETH HOLMES, an individual, RAMESH BALWANI, an individual, and DOES 1-10,

Defendants.
----------/

** CONFIDENTIAL **

VIDEOTAPED DEPOSITION OF MAX FOSQUE

Palo Alto, California

Wednesday, March 22, 2017

Reported by:
LORRIE L. MARCHANT, CSR No. 10523
RMR, CRR, CCRR, CRC

Job No. 120966

standard across -- a standard term used across the lab industry for enterprise software applications that are used by labs in clinical laboratories --

Q. Go ahead. Sorry.

A. -- to perform various functions in the laboratory. For example, reviewing patient results. For example, creating work lists for those in the laboratory to know what tests they have to run.

Q. When you started working on this, was this a point in time -- I think you mentioned September 2013?

A. M-hm.

Q. So by that point in time, at least the Palo Alto Walgreens location was up and running?

MR. BENEDETTO: Object to form.

THE WITNESS: In September 2013, the Palo Alto Walgreens was up and running.

BY MR. CHAN:

Q. In terms of actually doing patient samples?

A. It was my understanding that at that point these were still technology demonstrations. And it wasn't until October of 2013 that clinical patient samples were being tested.

Q. So in October of 2013, was LIS in place?

A. Correct.

Q. So what was your role with respect to LIS in fall of 2013?

A. The -- kind of the standard product manager role. You know, working on the application, developing requirements, communicating with developers, working with QA. Kind of the typical role that a product manager would play in a software business.

Q. For how long did you work on LIS?

A. I worked on LIS until the day that we stopped doing testing.

Q. What's the current status of LIS?

A. It is still operational. Still can be used to look up patient records If our laboratory directors need to do that.

Q. Okay. So -- and I'll ask you more detailed questions about that later.

But -- so other -- other projects?

A. I mean, I've worked on other software applications, but never really as the lead. LIS was the project that I mostly worked on.

Q. Your title, has that changed over time?

A. It has.

Q. How has it changed?

A. From product manager to senior product

manager.

Q. Did that come with different responsibilities?

A. The change to senior product manager, I believe, happened around the same time I started getting involved in software and taking more responsibility for software applications and, you know, working with lab operations.

Q. Has your supervisor -- your direct supervisor always been the same throughout?

A. No.

Q. How has that changed over time?

A. I was directly reporting to Christian, and then I was directly reporting to Sunny, and now I'm directly reporting to Shekar.

Q. What happened to make you switch from reporting directly to Christian to Sunny?

MR. BENEDETTO: Object to form.

THE WITNESS: I don't know exactly. Just my reporting structure was changed.

BY MR. CHAN:

Q. So, for example, it wasn't as If Christian got moved away to some other group and so, therefore, he physically couldn't be your direct supervisor anymore?

A. Again, I don't know the exact reasons.

Q. Or you got promoted so that you were at the same level as Christian?

A. I believe that the promotion to senior product manager happened around the same time that my reporting structure changed.

Q. Is Christian's title also senior product manager?

MR. BENEDETTO: Object to form.

THE WITNESS: I believe he's director of something. I'm not sure of his exact title.

BY MR. CHAN:

Q. And you stopped reporting to Sunny after he left the company?

MR. BENEDETTO: Object to form.

THE WITNESS: I believe around that time, yes.

BY MR. CHAN:

Q. And -- sorry. Who's your -- and the third person is your current supervisor?

A. Correct. Shekar.

Q. And what's his title?

A. I believe right now he is the head of software.

Q. How about people reporting to you? Has

that changed over time?

A. Yes.

Q. How did that change?

A. I've had a few individuals report to me over time.

Q. When you first started, did you have anybody reporting to you?

A. I did not.

Q. And so over time, who reported to you?

A. I had a woman named Ann Gottwalt report to me. She was a product manager. I had an individual named Henry Holbrook report to me as a product manager. An individual, Anam Kahn, currently reports to me, and an individual, Caitlin Hanson, currently reports to me.

Q. Those last two, are they also product -- project managers?

A. Correct.

Q. How about your compensation? Has that changed over time?

A. It has.

Q. What was the highest level of compensation you ever held?

A. The exact salary?

Q. Sure.

A. 180,000 per year.
Q. Base salary?
A. Yes.
Q. Have you ever received bonuses on top of your salary?
A. Not monetary, cash bonuses, no.
Q. Are you eligible for cash bonuses?
MR. BENEDETTO: Object to form.
THE WITNESS: To be honest, I don't even know.
BY MR. CHAN:
Q. But you received noncash compensation?
A. I have received noncash compensation, yes.
Q. What have you received?
A. I have received both options and some other -- like, stock units or -- I'm not sure of the exact -- RSUs, restricted stock units.
Q. The options that you were given, did they come all at once or at different times?
A. I received one installment of options.
Q. When was that?
A. I believe in fall of 2013.
Q. Was that in connection with any particular event for you?
MR. BENEDETTO: Object to form.

THE WITNESS: From my understanding, that was part of a company-wide review cycle.

BY MR. CHAN:

Q. And approximately how many options did you get?

A. 25,000.

Q. And none of that is vested?

MR. BENEDETTO: Object to form.

THE WITNESS: Honestly, I don't know.

BY MR. CHAN:

Q. And in terms -- do you ascribe, in your mind, a dollar value to those options?

A. I don't.

Q. You were also given RSUs?

A. Correct.

Q. How did you get those?

MR. BENEDETTO: Object to form.

THE WITNESS: It was my understanding that those were granted as part of, again, the company review cycle.

BY MR. CHAN:

Q. That same one when you got the options?

A. No.

Q. What year?

A. At a later point in time.

Q. What year?

A. I received an installment of RSUs, I believe, in fall of 2014, and another -- I believe another installment in 2015, but I'm not completely sure.

Q. How many RSUs in total?

A. I believe 50,000 in total.

Q. And does that translate to a particular number of shares?

MR. BENEDETTO: Object to form.

THE WITNESS: Again, I'm not sure.

BY MR. CHAN:

Q. Any other -- do you own any stock in Theranos?

MR. BENEDETTO: Object to form.

THE WITNESS: I don't believe so. Just the options.

BY MR. CHAN:

Q. Do any of your family members own stock in Theranos?

A. No.

Q. Have you had the review cycle for 2016 yet?

A. No. It's ongoing.

Q. Have you been told anything about any potential bonus or additional compensation in

connection with that?

A. I have not.

Q. And you're currently employed; right?

A. Correct.

Q. No plans to leave?

A. Not at the moment.

Q. You haven't been informed that you have -- you know, you might be part of a future round of reduction in force?

A. I have not.

MR. CHAN: Okay. Shall we take a break? We've been going for an hour straight. Let's break for five minutes, please.

THE VIDEOGRAPHER: Going off the record at 10:08.

(Recess taken, from 10:08 to 10:16.)

THE VIDEOGRAPHER: Back on the record at 10:16.

MR. CHAN: All right. I'm going to show you three documents. The first is what will be marked as Exhibit 459.

(Marked for identification purposes, Exhibit 459.)

MR. CHAN: The second as 460.

///

(Marked for identification purposes, Exhibit 460.)

MR. CHAN: And the third as 461.

(Marked for identification purposes, Exhibit 461.)

THE WITNESS: Do you want me to read through all of these?

MR. CHAN: Yeah, just enough to make sure you recognize them.

For the record, 459 is entitled "Defendant Theranos, Inc.'s Responses and Objections to Plaintiffs' First Set of Interrogatories."

460 is "Defendant Theranos, Inc.'s First Supplemental Responses and Objections to Plaintiffs' First Set of Interrogatories."

And 461 is "Defendant Theranos, Inc.'s Responses and Objections to Plaintiffs' Second Set of Interrogatories."

MS. RAINWATER: Is there another copy of 461? Thanks.

MR. CHAN: I'm also going to hang up the conference bridge at this point.

BY MR. CHAN:

Q. Do you recognize those three documents?

A. I recognize these two (indicating).

Q. Which two?

A. The 459 and 460. I don't recall If I've seen this one before.

Q. Does 461 have your signature at the back?

A. That would be a good place to check.

I have seen it before.

Q. So in what context have you seen these three interrogatory responses before?

A. The first -- this one and this one (indicating), I was --

Q. Which ones?

A. 459 and 460, I was involved in developing some of the responses. And 461, I believe I was involved in reviewing and may have been involved in developing some of the responses.

Q. Okay. We'll go through each of these.

But, in general, do you recall that at the end of your review and assistance with these interrogatory responses, that you had to sign a verification as to each?

A. Yes.

Q. To your understanding, what did you verify?

A. From my understanding, I was verifying kind of the -- you know, what I had been involved in and working on what I had knowledge of that was

contained in the documents.

Q. And also that what you were reviewing, to the best of your knowledge, was complete and accurate?

A. Subject to limitations that were set forth, yes, I believe the responses were true and accurate to the best of my knowledge.

Q. So when you -- but when you signed these verifications, you had no reason to think that anything in these three interrogatories was incorrect or inaccurate?

A. Nope.

Q. And you still don't as of today?

A. You know, to the best of my knowledge.

Q. Let's start with the 459. And specifically within 459, which is the first set of interrogatory responses, to the response to Interrogatory No. 18, which begins on page 46 of the document.

Take a minute to review it, and let me know when you're done reviewing the question and answer there.

A. Okay.

Q. Was this response to Interrogatory No. 18 one of the ones that you helped to draft?

A. A small piece of it, yes.

Q. Which piece of it do you recall helping to draft?

A. The piece that talks about the availability of test offerings differing by geography.

Q. On page 47?

A. Correct.

Q. Other than that piece and helping to draft that piece of it, do you recall reviewing the entire response?

A. I do.

Q. Focusing your -- let's go through this response, starting on page 46, where it says:

> "These requests seek a compilation of information that must be derived from Theranos's proprietary databases that contain patient testing data pertaining to millions of test results."

When the answer here refers to "proprietary databases," to your understanding, what does that refer to?

A. From my understanding, that refers to the LIS database and other lab databases.

Q. What other lab databases are there at Theranos?

A. There was a database used -- part of the

LABDAQ LIS application.

Q. How do you spell LABDAQ?

A. L-A-B-D-A-Q.

Q. What's the difference between LABDAQ and LIS?

A. LABDAQ is developed by a third party.

Q. Was there a difference in the use between those two within Theranos?

A. Yeah. I mean, moderate -- slight to moderate differences. They weren't used for exactly the same thing. They were used in parallel.

Q. The entire period of time?

A. No.

Q. Which periods of time were they used in parallel?

A. I believe from September 2013 through probably early to mid-2015.

Q. So LABDAQ stopped being used before LIS stopped being used?

A. That is my understanding.

Q. Why were there two lab databases being run in parallel?

MR. BENEDETTO: Object to form.

THE WITNESS: I don't really know the business reasons behind that.

BY MR. CHAN:

Q. Well, did you work on LABDAQ at all?

A. I did, yes.

Q. And did you have an opinion as to whether there should be two databases going at the same time?

A. Didn't hold a strong opinion.

Q. You never had a discussion with anyone internally about whether to do that or not?

A. From a -- kind of a business strategy standpoint? Not really.

Q. Did that mean that with respect to every potential data entry point that there would be duplicate effort?

A. No.

MR. BENEDETTO: Object to form.

BY MR. CHAN:

Q. Why is that?

A. They were just used for, you know, partly different purposes. Different data was flowing into the various applications. It was not a duplicative type of thing.

Q. So were there certain records that were stored in one database versus another?

A. That's correct.

Q. Which ones were stored in LABDAQ that were not stored in LIS?

A. There were some patient results that were stored in LABDAQ that were never stored in LIS.

Q. Was that dependent on a test or some other factor?

A. There were some factors.

Q. What were the factors that determined which database would hold which patient result?

A. Typically, LABDAQ was connected to one set of clinical analyzers. And when tests were performed on those clinical analyzers, results were uploaded directly to the LABDAQ application.

And there was a period of time where that was the -- kind of the last stop on the train, so to speak, for those results.

Q. Was there anything in common about those analyzers that were connected to LABDAQ?

MR. BENEDETTO: Object to form.

THE WITNESS: They were clinical analyzers.

BY MR. CHAN:

Q. Were they all analyzers manufactured by companies other than Theranos?

A. That's correct.

Q. Were there some records where the patient

result would feed into both LABDAQ and LIS?

A. That's correct.

Q. Even though it was done on the same machine?

MR. BENEDETTO: Object to form.

THE WITNESS: Results would be run on a machine. Results would be sent to LABDAQ. There was a direct interface between the machine and the LABDAQ application.

There was also an interface built between LABDAQ and our LIS system. So results would flow from the machine to LABDAQ and then finally through to our LIS system.

BY MR. CHAN:

Q. Oh, I see.

And was there some period of time where the flow from LABDAQ to LIS did not occur?

A. Yes.

Q. What period of time was that?

A. The beginning of when LABDAQ was launched until, I would say, May of 2014, on or abouts.

Q. Who -- who determined whether or not a particular machine would be interfaced with LABDAQ directly versus directly with LIS?

MR. BENEDETTO: Object to form.

THE WITNESS: From my understanding, it was the business, Sunny, the medical directors.

BY MR. CHAN:

Q. Was there a technological reason why that had to be so for particular machines?

MR. BENEDETTO: Object to form.

THE WITNESS: I honestly am not sure.

BY MR. CHAN:

Q. Well, for -- another way to ask it is, was there a period of time where a machine that previously was directly connected to LABDAQ was switched over to be directly connected to LIS?

A. I believe so, yes. Not a switch. They would just be connected to both.

Q. Is the connection some sort of network connection?

A. An interface, yeah.

Q. So if you today wanted to search for a particular patient record, can you rely solely on LIS to do that, or do you have to consult LABDAQ If some way?

MS. RAINWATER: Objection. Form.

THE WITNESS: That depends on the information you are trying to obtain.

///

BY MR. CHAN:

Q. So in what circumstances would you have to search both LABDAQ and LIS?

A. If you wanted to find a patient result, that result may exist in LIS, may exist in LABDAQ, so you would have to consult both.

Q. But in terms of any other components of a -- of a record, would you also have to search both?

MS. RAINWATER: Objection. Form.

THE WITNESS: If you wanted to find the reference range used for the result, for example, and the result only existed in LABDAQ, you would have to go in LABDAQ.

If you wanted to find the -- for example, the visit location where the -- the PSC where the visit was performed, all of that information is found in LIS. And this is because all patient visits were performed using the PSC application. So regardless of where the results finally ended up, the visit information is all found within that same database that LIS is connected to.

BY MR. CHAN:

Q. Are there some broad categories of kinds of tests where you know that the result is only

available, even today, in LABDAQ?

MR. BENEDETTO: Object to form.

THE WITNESS: Not really, no.

BY MR. CHAN:

Q. So it sounds like you pretty much have to run a query for any patient just to be sure?

A. I wouldn't necessarily say that. The time frame of when the visit occurred, the location of the visit, that could help you narrow it down considerably.

Q. So what's an example of a -- of a search parameter where, because of the location of the store or the date, that you can categorically rule out having to look for the patient result in LABDAQ?

A. For example, a patient who came in to a Phoenix location, and the sample was run in the Phoenix lab and all tests were performed in-house, those would never be found in LABDAQ.

Q. Why is that?

A. Because the Phoenix laboratory -- all results that were performed in the Phoenix laboratory were uploaded directly to LIS.

Q. What about with respect to lab tests that were run on a 3.5 device?

A. Those would never -- those would almost

would be in the databases besides Safeway, Walgreens and on-site?

A. Not -- not under the purview of the CLIA lab, from my understanding.

Q. Were there -- is there test data in either database associated with a non-CLIA test?

A. From my understanding -- well, there is data from other individuals. It was my understanding that those were technology demonstrations, so to speak.

And there's also some test data that's just, you know, fake data from a software perspective that we would use when doing production testing on the system.

Q. Would there be any R&D test-related data in either of these databases?

A. How do you define "R&D"?

Q. Well, for example, when proficiency testing was done on an analyzer.

A. I believe some of that, yes, that's found in LIS.

Q. Or validation testing on -- on human samples?

A. I don't believe validation testing is found in on LIS.

test ever done?

A. LIS does not have every test result ever obtained from a test performed by Theranos.

Q. Does it have test results performed by a third-party reference lab?

A. Yes.

Q. How does that get into the LIS system?

A. It could be one of many different ways.

Q. What are some of the ways?

A. Manual entry, for example.

Q. Is there a requirement or an SOP whereby the expectation is that a third-party result is input into LIS in some manner?

A. There were CLIA laboratory SOPs around the entry of patient results and around the entry of results associated with reference labs.

Q. Was the ultimate results of those -- intended result of those SOPs that the reference lab results be entered into LIS?

MR. BENEDETTO: Object to form.

THE WITNESS: The intent of the SOPs was to instruct the laboratory employees on how to go about entering the results and ensuring those results were exactly what the reference lab had sent to us.

///

DEPOSITION OFFICER'S CERTIFICATE

STATE OF CALIFORNIA)
) ss.
COUNTY OF SONOMA)

I, LORRIE L. MARCHANT, hereby certify: I am a duly qualified Certified Shorthand Reporter in the State of California, holder of Certificate Number CSR 10523 issued by the Court Reporters Board of California and which is in full force and effect. (Bus. & Prof. Section 8016)

I am not financially interested in this action and am not a relative or employee of any attorney of the parties, or of any of the parties. (Civ. Proc. Section 2025.320(a))

I am authorized to administer oaths or affirmations pursuant to California Code of Civil Procedure, Section 2093(b), and prior to being examined, the deponent was first duly sworn/affirmed by me. (Civ. Proc. Section 2025.320, 2025.540(a))

I am the deposition officer that stenographically recorded the testimony in the foregoing deposition and the foregoing transcript is a true record of the testimony given. (Civ. Proc. Section 2025.540(a))

I have not and shall not offer or provide any services or products to any party's attorney or third party who is financing all or part of the action without first offering same to all parties or their attorneys attending the deposition and making same available at the same time to all parties or their attorneys. (Civ. Proc. Section 2025.320(b))

I shall not provide any service or product consisting of the deposition officer's notations or comments regarding the demeanor of any witness, attorney or party present at the deposition to any party or any party's attorney or third party who is financing all or part of the action, nor shall I collect any personal identifying information about the witness as a service or product to be provided to any party or third party who is financing all or part of the action. (Civ. Proc. Section 2025.320(c))

Dated: March 22, 2017

_____

LORRIE L. MARCHANT, CSR NO. 10523
RMR, CRR, CCRR, CRC

EXHIBIT 26

In re Arizona Theranos, Inc. Litigation

Videotaped Deposition of

SEKHAR VARIAM

April 23, 2019

CONFIDENTIAL

UNDER THE PROTECTIVE ORDER

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Page 1

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

In re:)No. 2:16-cv-2138-HRH
)Consolidated with
ARIZONA THERANOS, INC.,)2:16-cv-2373-HRH
Litigation)2:16-cv-2660-HRH
)2:16-cv-2775-HRH
)-and-
)2:16-cv-3599-HRH
)

CONFIDENTIAL UNDER THE PROTECTIVE ORDER
VIDEOTAPED DEPOSITION OF SEKHAR VARIAM
San Francisco, California
April 23, 2019

REPORTED BY:
JOHNNA PIPER
CSR 11268
Job No. 10054958

Page 2

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

In re:)No. 2:16-cv-2138-HRH
)Consolidated with
ARIZONA THERANOS, INC.,)2:16-cv-2373-HRH
Litigation)2:16-cv-2660-HRH
)2:16-cv-2775-HRH
)-and-
)2:16-cv-3599-HRH
)

Videotaped deposition of SEKHAR VARIAM, Volume 1, taken on behalf of Plaintiffs, at Lieff, Cabraser, Heimann & Bernstein, 275 Battery Street, 29th Floor, San Francisco, California, beginning at 9:04 a.m. and ending at 12:16 p.m. on Tuesday, April 23, 2019, before JOHNNA PIPER, Certified Shorthand Reporter No. 11268.

Page 3

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Page 4

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Also Present: Steve Patapoff, videographer.

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which tests will be run on which device and that information would be residing in DB and eLabsDB.
BY MS. GARDNER:
Q. Was the determination regarding which device would be used made through an algorithm or in some other way?
A. There was --
MS. MCDOWELL: Objection. Lack of foundation.
BY MS. GARDNER:
Q. It's okay. You can answer.
A. There was an algorithm that was written to determine that.
Q. Okay. Would the algorithm be within one of these databases?
A. The algorithm was residing in the code. Not in this -- I think --
(Reporter requests clarification.)
THE WITNESS: So the -- a part of the algorithm was determined by a data that was residing on -- in this database, the TVA database, but a part of it was residing in the code, a source code written outside the database. So it used the data in the database to determine where the tests would have to be run. So it's a combination of data in

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the database and code written outside.
BY MS. GARDNER:
Q. Okay. Were you involved in writing that code?
A. Partially, yes, so . . .
Q. Did you change that code over time?
A. The code has changed, yes.
Q. Where -- I guess it's kind of a broad question, but how did you access the source code?
A. It was in -- checked into the Theranos system, so using Visual Studio. That is -- this is the tool, Visual Studio.
Q. Was it also saved on the J drive or elsewhere?
A. The source code was saved in Theranos source control using Microsoft Team Foundation Servers. And -- before we left we moved all the code to J drive.
Q. When you say "we" moved all the code to J drive, who do you mean?
A. I mean me -- so IncRev. We were asked to take a backup of all the code before we left so that it's -- you don't have to look at -- so they wanted all the things consolidated in the J drive.
Q. So do you mean all of the information from

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all of the Theranos systems was consolidated on the J drive?
A. Yes.
Q. Okay. All right. So the virtual analyzer has a list of devices used to run samples. You -- is that correct?
A. That's correct.
Q. Did it include every device at -- within Theranos labs?
MS. MCDOWELL: Objection. Lack of foundation.
BY MS. GARDNER:
Q. It's okay.
A. In my understanding, it did contain.
Q. Okay. Were all of the devices that were used to run patient test samples able to communicate electronically with the database?
A. The -- not directly. They had to use -- so the database is behind firewalls, so it uses a service to connect to the database -- a web service to connect.
Q. But all of the devices could connect through some means?
A. Through some means, yes, as far as I remember. I don't know if there were any -- I don't

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remember if there were any manual devices, so -- in which case they might have just entered the results directly, so . . .
Q. Okay. Other than devices and information about which samples were run or should be run on a given device, is there other information in the TVA database?
A. The -- the data to determine which tests need to be run on which device, the data that was underlying the algorithm, the raw signals from the devices, as I mentioned before, and -- it also contained -- so since it contained the results of the runs, it would also contain results of QC runs if any.
Q. When you say QC runs if any, do you -- why do you say if any?
A. No. So in the sense -- the QC runs and then -- I don't know how they were entered, so -- I don't know how the records were kept, but -- so -- from a code perspective, we didn't know if it was -- technicians would determine if a run was QC or not -- not a patient run.
Q. Gotcha.
A. And we don't know -- from a developer standpoint, I don't know that.

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Q. Okay. And -- other than what you've talked about so far, is there other information in the TVA database?
A. I don't -- it also contained sample images. There was one table which contained images.
Q. Were there images for every sample or just some samples?
A. Some --
MS. MCDOWELL: Objection. Lack of foundation.
THE WITNESS: I don't -- I don't remember -- but we just had the database to store the images, so -- I know there were images for some samples for sure. I don't think there were images for every sample --
BY MS. GARDNER:
Q. Okay.
A. -- so . . .
Q. And when you mentioned the QC run results, what data was stored in connection with a QC run?
A. So whether the run was -- so there were some devices for which we could specify of it as a QC run, and for that we know that the QC run and the results for the QC run and the results for some of the rules -- Westgard rules that are applied. The

Page 50

QC -- QC has some -- QC runs have some rules, and the results of some of those rules when applied to a QC run.
Q. I couldn't understand something you said just now. It sounded like Vesgard.
A. Westgard, W-E-S-D -- S-D-G-A-R-D [sic].
Q. What is Westgard?
A. Westgard is a statistician who defined the rules for how a QC run will -- whether it falls within one standard deviation, two standard deviation of the sample, the --
Q. Okay. Would there be any GUID associated with the QC run data?
A. Yes. But a QC run was also run like a normal -- it would be run like a normal run, so -- the business process used I'm not clearly -- I don't know what process was used for each device, so -- there was one particular set of devices for which the QC run was there, that much I know, so I think they would have a GUID for the runs.
Q. Okay. And that's a GUID for the sample that was run?
A. I think it was a GUID for the whole run, and I guess it -- each run would be associated with a sample --

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Q. Okay.
A. -- so . . .
Q. And are these samples then -- is the GUID associated with the person whose sample it is or something else?
A. QC runs are not for any person, so it's just for a -- a QC -- known QC sample is put on the device, so -- it's not associated with any person.
Q. Okay. All right. Other than QC run data and the other things you've mentioned --
A. Yeah, I don't recall anything else being in the --
(Reporter requests clarification.)
THE WITNESS: I don't recall any other information that is in the TVA database right now.
BY MS. GARDNER:
Q. All right. The next one on the list here is the X-I-F-I-N database. What is that?
A. It's the XifinDB. I have not worked on this database, so it was used -- as far as I remember, this was used to store the financial information for all the orders and -- Xifin system was a system that was used for I think clearing, but I have never worked on this, so -- FinDB was designed to replace the XifinDB, so I think Xifin

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should -- may have some information on the price of the order fulfillment, but I'm not -- I've never seen this database myself.
Q. All right. Thank you.
The only folder we haven't yet discussed inside screenshot number one here is entitled "All keys_certs," C-E-R-T-S. Do you see that?
A. Yes.
Q. All right. I will represent to you -- actually, I don't have to. I've got it on the projector here. If you open that, you will see the two subfolders that show up in the second screenshot on Exhibit Variam 2.
A. Yes.
Q. And they are entitled "Primary 71" and "Secondary 72."
A. Yes.
Q. What are these?
A. So the database was installed on two servers where one -- so there were two IP addresses, 172.20.1.71 and 172.20.1.72. The secondary server acted as a failover to the primary in case the primary server went down. The -- all the requests would be routed to the secondary server and the data was automatically synced between these two servers.

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So that was the two servers. So -- Primary 71 and 72 both contain the same database, but it's just continuously synced between each other.
Q. Okay. What is the relationship between Primary 71 and 72 and the databases that we've been talking about this morning?
A. So Primary 71 and 72 are the underlying SQL Server instances, and the same database is installed on 71. SQL Server replicates the database onto 72. So this data will be exactly same on both the -- both the servers.
Q. And -- just to understand --
A. I'm sorry.
Q. -- do these two servers contain all of the databases that we have been discussing today?
A. That's correct.
Q. Okay. So if you click into Primary 71 here, I will represent that you'll see the contents on the fourth screenshot of Exhibit Number 2 --
A. Uh-huh.
Q. -- and likewise, if you click into Secondary 72, you'll see the contents on the third screenshot of Exhibit Number 2. Is there enough information here to access the contents of the databases, the off DB, DashboardDB, and so on that

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we have been discussing today?
A. There -- there should be, provided you have a SQL Server Enterprise edition software installed. And the instructions also are in the document that we had submitted, instructions to use these -- to access the database.
Q. Okay. And when you say that you submitted the instructions, you mean -- are you talk -- just go ahead and repeat what you -- what you meant there.
A. So before we -- before I -- my contact with Theranos ended we had submitted a document which contained instructions to use these keys to decrypt these databases in a Word -- the document that was prepared by Siva and the DevOps team, we passed on that to Theranos.
Q. When you say these keys, what here is a key?
A. So I'm -- this is something I have not worked on, but based on my knowledge, each server has a master key, so the master key is different for each of the two servers, and within that master key I think you -- after using the master key you generate some -- a separate certificate, and databases are encrypted with these certificates

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using -- so if you have to restore this database to a different server, you need to be able to import -- so I'm not hundred percent sure because it's in the instructions, I have never done it myself, but based on my knowledge, I think you import the master key to the new server and then, based on that, you should be able to import these certificates in the private key also to the new server. And then, if you restore these databases on that new server, you should be able to read the databases.
Q. All right. Is the master key something that you see here before you?
A. The master key -- I think it should be the master key file.
Q. Okay. And the private key?
A. Is the .pfx, privatekey.pfx.
Q. Okay. And would you expect the master key file that appears inside the subfolder labeled Primary 71 to work on Secondary 72?
A. I'm not fully sure of that and -- but if you go to -- this is something that you would also get in Microsoft SQL Server documentation, because this is not anything related to this particular application.
Q. Okay.

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MS. GARDNER: All right. I think we can take a break.
THE VIDEOGRAPHER: Going off the record at 10:33.
(Recess taken.)
THE VIDEOGRAPHER: Back on the record at 10:49.
BY MS. GARDNER:
Q. All right. So I am going to the contents of this hard drive again to the topmost folder entering the LIS folder, the latest prod DB backups folder, and I've once again opened up the subfolder that appears in the first screenshot of Exhibit Number 2. And I will ask you, Sekhar --
A. Yes.
Q. -- Sekhar, if you wanted to restore these servers and you had this data in front of you, what would you do?
A. I don't -- I don't know about restoring the servers, because that was Theranos IT, but what usually you would do is you would need these keys restored on any server with SQL Server Enterprise edition installed, and you can import these to -- the certificate and the private key, or either one of -- I don't know both of them, but into that

CERTIFICATE OF REPORTER

I, JOHNNA PIPER, a Certified Shorthand Reporter, hereby certify that the witness in the foregoing deposition was by me duly sworn to tell the truth, the whole truth and nothing but the truth in the within-entitled cause;

That said deposition was taken down in shorthand by me, a disinterested person, at the time and place therein stated, and that the testimony of the said witness was thereafter reduced to typewriting, by computer, under my direction and supervision;

I further certify that I am not of counsel or attorney for either or any of the parties to the said deposition nor in any way interested in the event of this cause and that I am not related to any of the parties thereto.

Further, that if the foregoing pertains to the original transcript of a deposition in a federal case, before completion of the proceedings, review of the transcript [ ] was [X] was not requested.

DATED: May 6, 2019

JOHNNA PIPER, CSR 11268

DECLARATION UNDER PENALTY OF PERJURY

Case Name: In re Arizona Theranos, Inc. Litigation
Date of Deposition: 04/23/2019
Job No.: 10054958

I, SEKHAR VARIAM, hereby certify under penalty of perjury under the laws of the State of _____ that the foregoing is true and correct.

Executed this _____ day of _____, 2019, at _____.

_____
SEKHAR VARIAM

NOTARIZATION (If Required)
State of _____
County of _____
Subscribed and sworn to (or affirmed) before me on this _____ day of _____, 20__, by_____, proved to me on the basis of satisfactory evidence to be the person who appeared before me.
Signature: _____ (Seal)

DEPOSITION ERRATA SHEET

Case Name: In re Arizona Theranos, Inc. Litigation
Name of Witness: Sekhar Variam
Date of Deposition: 04/23/2019
Job No.: 10054958
Reason Codes: 1. To clarify the record.
2. To conform to the facts.
3. To correct transcription errors.

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DEPOSITION ERRATA SHEET

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_____ Subject to the above changes, I certify that the transcript is true and correct
_____ No changes have been made. I certify that the transcript is true and correct.

_____
SEKHAR VARIAM

EXHIBIT 27

From: Benedetto, Matthew
Sent: Monday, June 4, 2018 4:40 PM EDT
To: Davies, Christopher; Romeo, Mike; Mugmon, Michael; Moran, Katie
CC: Gautam, Zubin; Maali, Sahar; Smith, Robert Kingsley; Lewis, Jessica
Subject: RE: Theranos -- Summary of 5/23/18 Call with the DOJ

Redacted

From: Davies, Christopher
Sent: Thursday, May 24, 2018 5:43 AM
To: Romeo, Mike ; Mugmon, Michael ; Benedetto, Matthew ; Moran, Katie
Cc: Gautam, Zubin ; Maali, Sahar
Subject: RE: Theranos -- Summary of 5/23/18 Call with the DOJ

Redacted

From: Romeo, Mike
Sent: Wednesday, May 23, 2018 11:35 PM
To: David Taylor (dtaylor@theranos.com) <dtaylor@theranos.com>; Davies, Christopher <Christopher.Davies@wilmerhale.com>; Mugmon, Michael <Michael.Mugmon@wilmerhale.com>; Benedetto, Matthew <Matthew.Benedetto@wilmerhale.com>; Moran, Katie <Katie.Moran@wilmerhale.com>
Cc: Gautam, Zubin <Zubin.Gautam@wilmerhale.com>; Maali, Sahar <Sahar.Maali@wilmerhale.com>
Subject: Theranos -- Summary of 5/23/18 Call with the DOJ

Privileged and Confidential
Attorney-Client Communication

Hello All,

This afternoon, Michael, Matt, Katie, and I talked with Jeff Schenk and John Bostic to follow up on some open items from our call last Thursday (the 17th). Broadly, we covered the following three topics: Redacted

Redacted

Redacted 3) production of additional items requested in the DOJ's April 20th subpoena (lab data Redacted

Redacted

Redacted

5. We promised to explore options for producing additional data showing how the tests for all Theranos customers were conducted (*i.e.*, data allowing the DOJ to understand which device was used to process a given customer's test or tests).

Redacted

III. Our Production of Additional Items Requested in the DOJ's April 20th Subpoena (Lab Data) Redacted

Redacted

e. Lab data: We discussed Jeff and John's request for lab data that would show "how a given assay had been run;" in other words, what device was used to process the test a given patient received. We told Jeff and John that unfortunately, it was not feasible to simply provide a copy of the LIS database, because they would not have the experience with the system to understand how to compile the data they wanted. After a good deal of back and forth, Jeff and John asked whether it would be possible to provide them with two data compilations: (1) a table that correlates the accession number of a test ordered (this number is stored in LIS) with the name of the customer who ordered the test, and (2) a second spreadsheet which would list every test Theranos had run, together with the result and the analyzer used to run the test. Jeff and John could then match up the second table with the first table to determine how a given customer's tests were performed. We indicated that given the Company's resource constraints, we could not guarantee this could be done, but we would explore what was feasible and circle back to them on this point.

f. Finally, Jeff and John indicated they would provide us with an updated subpoena requesting patients' test results as stored in LIS which does not include the prior subpoena's carve out for HIV test results, so that we can produce the full compilation of LIS test reports we have gathered.

Redacted

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EXHIBIT 28

United States Attorney
Northern District of California

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October 29, 2020

By Email

Lance Wade, Esq.
Kevin Downey, Esq.
Amy Saharia, Esq.
Katie Trefz, Esq.
Williams & Connolly LLP
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Washington, DC 20005

Re: *United States v. Holmes*, CR 18-258 EJD

Dear Counsel:

Pursuant to your requests for discovery, we write to alert you to the following information, which you may view as potential *Brady*, *Giglio*, or *Jencks* information. This supplements our letter to you dated July 9, 2019. By making these disclosures, we do not necessarily agree that this information is responsive to Rule 16, *Brady*, *Giglio*, or *Jencks*, nor do we waive any applicable privilege or protection.

* * * * *

1. Government notes of a phone call with Pete Skinner on or about January 28, 2016, state in part:

> privately held
> few SHDs
> sophisticated
> employees
> no public offering
>
> tech
> prop – h'ware, software, chem, protocol
> . . . .
> software enables TSPU and larger h'ware to hook up w/ cloud so machine can be used remotely & results viewed remotely
> big data anal.

46. On or about October 5, 2018, the ALS supervisor advised attorneys for the government and the government paralegal about issues surrounding the hard drive. She noted she had discussions with her unit, the IT department, and the LTSC. She said the drive does not contain material which could be processed in house or by the LTSC. She said the drive contains 12 BAK files totaling about 830 gigabytes. She said the .bak extension indicates that the files were most likely backup files for a Microsoft SQL database. She said if that was correct such files would be used to restore database backups on a Microsoft SQL Server. She said .bak is a common extension and without documentation of what the drive was meant to contain she could only make an educated guess that these were database backups. She said because they were archive files the size of the data could increase when restored. She said the material was not provided to the USAO in a format that can be extracted, viewed, or processed by available software. She said the LTSC's EDD [electronic data discovery] software can only digest SQL.bak files if they are under 300 mb. She suggested a possible route forward of pushing the producing party to see if the party could be persuaded to produce in a manner that can be viewed and processed in a standard way rather than an unspecified archive format the government could not access. She suggested encouraging the producing party to consider handing over its physical SQL server and setting it up in a workroom. She suggested checking with the FBI or other agencies to see if they have resources that can process large SQL database archives. She suggested identifying a vendor who could process the material and noted the data size and labor cost could be staggering. She offered to set up a call or meeting to discuss the issues further.

47. On or about October 30, 2018, the government paralegal advised the ALS supervisor she had met with attorneys for the government and the group decided to pursue the options of pushing the producing party to see if it could be persuaded to produce in a manner that can be viewed and processed in a standard way rather than an unspecified archive format the government could not access and checking with the FBI or other agencies to see if they have resources that can process large SQL database archives. The government paralegal also advised the ALS supervisor to return the hard drive when she had a chance. Around that time, the ALS supervisor did so. The hard drive remained in the possession of the government paralegal until around the spring of 2020.

48. In approximately October and November of 2020, counsel for the government was in contact with counsel for the assignee at the Dorsey law firm on a variety of topics. During those discussions, government counsel noted that the government had been unable to access the copy of the LIS database produced by Theranos. Assignee counsel expressed a lack of surprise that the government was having difficulty accessing the database, and offered to investigate whether the assignee had the database in a different form that would facilitate the government's access. During a subsequent conversation, assignee counsel reported back to the government that it had been unable to locate an alternative version of the LIS database that would allow access. Assignee counsel also informed government counsel that the LIS database was encrypted and that the assignee lacked the means to decrypt it. Assignee counsel opined that Sunny Balwani would likely be able to decrypt the database, but could not identify anyone else who they thought could accomplish the task.

49. On or about January 14, 2019, the government paralegal advised attorneys for the government that ALS had tried to process the hard drive but does not have the software to process the discovery and proposed possible options of producing a native version, involving the

Very truly yours,

STEPHANIE M. HINDS
Attorney for the United States,
Acting Under Authority Conferred
By 28 U.S.C. § 515

/s Robert S. Leach

ROBERT S. LEACH
JEFFREY SCHENK
JOHN C. BOSTIC
VANESSA BAEHR-JONES
Assistant United States Attorneys

cc Jeff Coopersmith, Esq. (by email)

EXHIBIT 29

United States Attorney
Northern District of California

1301 Clay Street, Suite 340S
Oakland, California 94612

(510) 637-3680
Fax: (510) 637-3724

September 28, 2020

By Email

Lance Wade, Esq.
Kevin Downey, Esq.
Katie Trefz, Esq.
Amy Saharia, Esq.
Williams & Connolly LLP
725 Twelfth Street, N.W.
Washington, DC 20005

Re: *United States v. Holmes*, CR 18-258 EJD

Dear Counsel,

On March 6, 2020, and April 3, 2020, and through our discovery letters, we notified you of evidence crimes, wrongs, or other acts the government may seek to introduce at trial. We write to supplement those disclosures. By providing this disclosure, the government is not conceding that the evidence described below (or previously) is properly considered Rule 404(b) evidence or is admissible only under the provisions of Rule 404(b). The government may also assert that this evidence is admissible as direct evidence of the charged conduct, that it is inextricably intertwined with the events charged in the operative Indictment, that it shows a continuing course of conduct otherwise admissible under Rules 401 and 402, or that it simply is not subject to Rule 404(b). We make these disclosures out of an abundance of caution and to avoid surprise about the government's intentions. In addition to the evidence expressly cited below, the government reserves the right to admit alternative versions of the cited items, additional evidence needed to place the cited evidence in context, and other equivalent and similar evidence of the same acts.

With that in mind, we notify you as follows:

/ /

its activities. The evidence also shows she was independent, not under the control of Balwani, as she and Dr. Mechanic suggest, and capable of forming intent to defraud.

During the fraud, Holmes traveled on corporate jets and in luxury vehicles and stayed in luxury hotels. *See, e.g.*, SEC-USAO-EPROD-001314171 (1/27/2015 travel on Flite logistics aircraft and landmark limousine); SEC-USAO-EPROD-002150649 (discussing search for best five star hotels, whether another suite needs to be reserved for Balwani, invite to Clinton Foundation, and internal Theranos meetings); SEC-USAO-EPROD-003730862; SEC-USAO-EPROD-003730866. The evidence is offered for the permitted purpose of motive, intent, preparation, plan, knowledge, absence of mistake, and lack of accident. Holmes's receipt of benefits from Theranos tends to show she had a financial incentive to commit the offenses, exercised control over Theranos, and was aware of its activities. It disproves Holmes's pubic suggestion and investor pitch that she was not motivated by money or acted for altruistic purposes. The evidence also shows she was independent, not under the control of Balwani, as she and Dr. Mechanic suggest, and capable of forming intent to defraud.

In or around September 2014, Holmes suggested at a TedMed conference her uncle's death was the inspiration for Theranos and that he died suddenly. *See, e.g.*, SEC-USAO-EPROD-000705421 (2/28/2016 email from E. Holmes to D. Edlin/E. Holmes stating that uncle's death was not sudden); SEC-USAO-EPROD-001205162. The evidence is offered for the permitted purpose of motive, intent, preparation, plan, knowledge, absence of mistake, and lack of accident. Such evidence disproves Holmes's pubic suggestion and investor pitch that she was not motivated by money and acted for altruistic purposes. The evidence also shows she was independent, not under the control of Balwani, as she and Dr. Mechanic suggest, and capable of forming intent to defraud.

Balwani's Lamborghini or Porsche bore the license plate DASKAPITAL. US-REPORTS-0013672. The evidence is offered for the permitted purpose of motive and intent.

XXII. Concealing the romantic relationship between Holmes and Balwani from investors and others.

The government may offer evidence of the following:

- Testimony by Holmes that she never told investors that she and Balwani had a romantic relationship. SEC-TX-000005499.

- Statements by Callie Rosendin that, sometime between March 2011 and July 2012, despite discouraging interpersonal relationships amongst Theranos employees, Holmes and Balwani were involved in a romantic relationship. Approximately three to four months into Rosendin's employment at Theranos, Balwani went to her and told her to keep his relationship with Holmes quiet. US-REPORTS-0002366.

- Statements by Jeff Blickman that he knew Balwani and Holmes were dating before Blickman started at Theranos. Blickman was under the impression their

EPROD-000068053; SEC-USAO-EPROD-000068054; SEC-USAO2-EPROD-000041814; SEC-USAO2-EPROD-000041815; SEC-USAO-EPROD-001224372.

***

The evidence is offered for the permitted purpose of motive, intent, preparation, plan, knowledge, absence of mistake, and lack of accident, as well as the existence of the conspiracy. Among other things, evidence that Holmes and Balwani did not disclose the relationship tends to show the agreement and joint plan. Such evidence tends to show intent – Holmes and Balwani feared that if investors knew it would raise questions about Balwani's role and qualifications. Such evidence is relevant to consciousness of guilt – public knowledge would undermine Holmes's public image that she lived an austere life devoted only to Theranos. Such evidence is relevant to the materiality of statements made to investors. Such evidence is also related to claims that Holmes and/or Balwani relied on the other and/or claims that because of a mental disease or defect she was unable to form intent to defraud.

***

The government reserves the right to introduce additional evidence covered by its previous disclosures, and further reserves the right to amend this notice in advance of trial based on its continuing investigation and trial preparation.

Very truly yours,

ADAM A. REEVES
Attorney for the United States,
Acting Under Authority Conferred
By 28 U.S.C. § 515

/s/

_____
ROBERT S. LEACH
JEFFREY SCHENK
JOHN C. BOSTIC
VANESSA BAEHR-JONES
Assistant United States Attorneys

Cc Jeffrey Coopersmith, Esq. (by email)

EXHIBIT 30

Walsh, Amy

From: Leach, Robert (USACAN) <Robert.Leach@usdoj.gov>
Sent: Thursday, November 11, 2021 5:05 PM
To: Walsh, Amy; Schenk, Jeffrey (USACAN); Bostic, John (USACAN); Volkar, Kelly (USACAN)
Cc: Coopersmith, Jeffrey; Cazares, Stephen; Schuricht, Sachi; Estrada, Shawn
Subject: RE: USA v. Balwani, No. 5:18-cr-00258-EJD

Dear Amy,

Thanks for following up. We may offer evidence in category #1. With respect to category #2, we will be in a better position to let you know after competition of the Holmes trial. I suggest we revisit that issue then.

Best regards,
Bob

From: Walsh, Amy <awalsh@orrick.com>
Sent: Thursday, November 11, 2021 1:31 PM
To: Schenk, Jeffrey (USACAN) <JSchenk@usa.doj.gov>; Leach, Robert (USACAN) <RLeach@usa.doj.gov>; Bostic, John (USACAN) <jbostic@usa.doj.gov>; Volkar, Kelly (USACAN) <KVolkar@usa.doj.gov>
Cc: Coopersmith, Jeffrey <jcoopersmith@orrick.com>; Cazares, Stephen <scazares@orrick.com>; Schuricht, Sachi <sschuricht@orrick.com>; Estrada, Shawn <sestrada@orrick.com>
Subject: [EXTERNAL] RE: USA v. Balwani, No. 5:18-cr-00258-EJD

All, I'm following up on the questions below.

Best,
Amy

From: Walsh, Amy <awalsh@orrick.com>
Sent: Friday, November 5, 2021 2:34 PM
To: jeffrey.b.schenk@usdoj.gov; robert.leach@usdoj.gov; john.bostic@usdoj.gov; kelly.volkar@usdoj.gov
Cc: Coopersmith, Jeffrey <jcoopersmith@orrick.com>; Cazares, Stephen <scazares@orrick.com>; Schuricht, Sachi <sschuricht@orrick.com>; Estrada, Shawn <sestrada@orrick.com>
Subject: USA v. Balwani, No. 5:18-cr-00258-EJD

Dear Counsel,
In preparation for filing motions in limine in the Balwani case on November 19th, we write to ask whether the government intends to offer the following items into evidence during Mr. Balwani's trial.

1. Evidence that Mr. Balwani's license plate allegedly contained the words "DASKAPITAL." *See* Letter from the Government to Lance Wade, Esq. (September 28, 2020) at 83.

2. The following text string from Government Exhibit 5387C that was admitted into evidence in the Holmes trial without objection from the defense. Please let us know if the government intends to admit this portion of Government Exhibit 5387C at Mr. Balwani's trial, and if so, what the theory of relevance is regarding the references to "death and sex" and "murder" highlighted below.

- Government Exhibit 5387C, admitted on October 14, 2021 during direct examination of Nimesh Jhaveri (Holmes Trial Tr. 3634:21 – 3635:20):
    - Holmes: "I am comfortable with saying the death and sex thing to Rupert bc it makes the point."
    - Balwani: "Don't."
    - Holmes: "Don't what?"
    - Balwani: "Don't make the death and sex point. Not ok."
    - Holmes: "Challenge is you saw how everyone reacted in press to me not meeting with him."
    - Holmes: "They didn't think him challenging me on patients was remotely a good reason not to meet with him."
    - Balwani: "But we have enuff points to say I didn't meet with him because of his false accusations and didn't have to meet with someone who was attacking me without even meeting with me. For example patents."
    - Balwani: "I wouldn't open up use personal life or murder because enough people on Twitter will assume that there is something there."
    - Balwani: "It's filth."
    - Balwani: "And we need to get out of flirty."
    - Balwani: "Filth."
    - Holmes: "Agree for sure on outside world. Even when Rupert to make point."
    - Balwani: "If u feel strongly about murder. But not personal life."
    - Balwani: "I think it is important to send this email but doesn't help with public beating. All our partners are bailing one at a time and same with our investors."

We may have additional questions as we continue to prepare our motions in order to avoid unnecessary motion practice.

Best regards,
Amy

Amy Walsh
Partner
White Collar Litigation, Investigations & Compliance

Orrick
New York
[redacted]
Bio: https://www.orrick.com/People/4/0/A/Amy-Walsh
awalsh@orrick.com

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EXHIBIT 31

Record	Type	Message Sent Date/Time	Message	Sender / Author	Recipient(s)	ChatID	Attachments
Holmes_iPhone_iMessage-MMS-SMS_027872	iMessage	3/10/2015 9:26:53 PM	We have an opportunity to put telemedicine in our contract with wag.	Sunny Balwani (	Elizabeth Holmes		
Holmes_iPhone_iMessage-MMS-SMS_027873	iMessage	3/10/2015 9:30:57 PM	We should nail that.	Elizabeth Holmes	Sunny Balwani (		
Holmes_iPhone_iMessage-MMS-SMS_027871	iMessage	3/10/2015 9:31:10 PM	And actually kick it off in our meeting with mayo	Elizabeth Holmes	Sunny Balwani (		
Holmes_iPhone_iMessage-MMS-SMS_027874	iMessage	3/10/2015 9:31:15 PM	And possibly Cleveland	Elizabeth Holmes	Sunny Balwani (		
Holmes_iPhone_iMessage-MMS-SMS_027877	iMessage	3/10/2015 9:31:23 PM	And then build the team here as we hire	Elizabeth Holmes	Sunny Balwani (		
Holmes_iPhone_iMessage-MMS-SMS_027876	iMessage	3/10/2015 9:31:33 PM	They won't be ready overnight anyway	Elizabeth Holmes	Sunny Balwani (		
Holmes_iPhone_iMessage-MMS-SMS_027878	iMessage	3/10/2015 9:31:39 PM	Cleveland clinic.	Sunny Balwani (	Elizabeth Holmes		
Holmes_iPhone_iMessage-MMS-SMS_027875	iMessage	3/10/2015 9:32:07 PM	Yes	Elizabeth Holmes	Sunny Balwani (		
Holmes_iPhone_iMessage-MMS-SMS_027879	iMessage	3/10/2015 9:32:10 PM	We will talk. We will bring this up and negotiate as last thin once all else is done.	Sunny Balwani (	Elizabeth Holmes		
Holmes_iPhone_iMessage-MMS-SMS_027883	iMessage	3/10/2015 9:32:16 PM	Yes	Elizabeth Holmes	Sunny Balwani (		
Holmes_iPhone_iMessage-MMS-SMS_027882	iMessage	3/10/2015 9:32:19 PM	I opened the door.	Sunny Balwani (	Elizabeth Holmes		
Holmes_iPhone_iMessage-MMS-SMS_027881	iMessage	3/10/2015 9:32:27 PM	Great	Elizabeth Holmes	Sunny Balwani (		
Holmes_iPhone_iMessage-MMS-SMS_027880	iMessage	3/10/2015 9:32:32 PM	Will tell u more in person.	Sunny Balwani (	Elizabeth Holmes		
Holmes_iPhone_iMessage-MMS-SMS_027886	iMessage	3/10/2015 9:32:36 PM	K	Elizabeth Holmes	Sunny Balwani (		
Holmes_iPhone_iMessage-MMS-SMS_027884	iMessage	3/10/2015 9:32:48 PM	They were drooling over Cleveland clinic announcement	Sunny Balwani	Elizabeth Holmes		
Holmes_iPhone_iMessage-MMS-SMS_027885	iMessage	3/10/2015 9:32:48 PM	We did tester	Sunny Balwani	Elizabeth Holmes		
Holmes_iPhone_iMessage-MMS-SMS_027887	iMessage	3/10/2015 9:32:48 PM	Yesterday	Sunny Balwani	Elizabeth Holmes		
Holmes_iPhone_iMessage-MMS-SMS_027888	iMessage	3/10/2015 9:33:45 PM	Everyone is	Elizabeth Holmes	Sunny Balwani (		
Holmes_iPhone_iMessage-MMS-SMS_027889	iMessage	3/10/2015 9:34:03 PM	Hopefully they're off peer review	Elizabeth Holmes	Sunny Balwani (		
Holmes_iPhone_iMessage-MMS-SMS_027890	iMessage	3/10/2015 9:34:20 PM	Which is why we need to do good by Cleveland clinic	Sunny Balwani (	Elizabeth Holmes		
Holmes_iPhone_iMessage-MMS-SMS_027891	iMessage	3/10/2015 9:34:26 PM	Yes. Off the table.	Sunny Balwani (	Elizabeth Holmes		
Holmes_iPhone_iMessage-MMS-SMS_027893	iMessage	3/10/2015 9:42:38 PM	Exactly	Elizabeth Holmes	Sunny Balwani (		
Holmes_iPhone_iMessage-MMS-SMS_027895	iMessage	3/10/2015 9:42:48 PM	On Cleveland clinic	Elizabeth Holmes	Sunny Balwani (		

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Fed. R. Crim. P. 6(e) material

Record	Type	Message Sent Date/Time	Message	Sender / Author	Recipient(s)	ChatID	Attachments
Holmes_iPhone_iMessage-MMS-SMS_029814	iMessage	4/9/2015 2:52:48 AM	Going thru cvs contract. We can't work with wag or cvs. Both are same.	Sunny Balwani (-	Elizabeth Holmes		
Holmes_iPhone_iMessage-MMS-SMS_029816	iMessage	4/9/2015 2:52:48 AM	And swy	Sunny Balwani (-	Elizabeth Holmes		
Holmes_iPhone_iMessage-MMS-SMS_029817	iMessage	4/9/2015 3:00:44 AM	Can't forget that	Elizabeth Holmes	Sunny Balwani (		
Holmes_iPhone_iMessage-MMS-SMS_029818	iMessage	4/9/2015 3:01:11 AM	We need to think thru our discussion on this topic	Sunny Balwani (-	Elizabeth Holmes		
Holmes_iPhone_iMessage-MMS-SMS_029819	iMessage	4/9/2015 3:03:11 AM	Meaning tomorrow's?	Elizabeth Holmes	Sunny Balwani (-		
Holmes_iPhone_iMessage-MMS-SMS_029821	iMessage	4/9/2015 3:03:28 AM	No. Our own stores.	Sunny Balwani	Elizabeth Holmes		
Holmes_iPhone_iMessage-MMS-SMS_029820	iMessage	4/9/2015 3:05:19 AM	Exactly.	Elizabeth Holmes	Sunny Balwani (		
Holmes_iPhone_iMessage-MMS-SMS_029822	iMessage	4/9/2015 3:05:36 AM	I am thinking. It will depend on discussion tomorrow with wag	Sunny Balwani (+	Elizabeth Holmes		

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Fed. R. Crim. P. 6(e) material

Record	Type	Message Sent Date/Time	Message	Sender / Author	Recipient(s)	ChatID	Attachments
Holmes_iPhone_iMessage-MMS-SMS_029901	iMessage	4/9/2015 8:22:18 PM	If contract terms and we don't have 1000 stores. What happens to 50m remaining innovation payment	Sunny Balwani (	Elizabeth Holmes		
Holmes_iPhone_iMessage-MMS-SMS_029906	iMessage	4/9/2015 8:43:03 PM	Depends on why terms	Elizabeth Holmes	Sunny Balwani (		
Holmes_iPhone_iMessage-MMS-SMS_029909	iMessage	4/9/2015 8:54:40 PM	Scale now if need	Elizabeth Holmes	Sunny Balwani (		
Holmes_iPhone_iMessage-MMS-SMS_029908	iMessage	4/9/2015 8:59:21 PM	So force build 1000 stores? I don't think that's intelligent.	Sunny Balwani (	Elizabeth Holmes		
Holmes_iPhone_iMessage-MMS-SMS_029911	iMessage	4/9/2015 9:00:00 PM	With contract expiring in August 2017 means building out 1000 by feb 2016. Not good for us	Sunny Balwani (	Elizabeth Holmes		
Holmes_iPhone_iMessage-MMS-SMS_029912	iMessage	4/9/2015 9:08:22 PM	There are equal number of cvs and wag in Ny state btw.	Sunny Balwani (	Elizabeth Holmes		

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Fed. R. Crim. P. 6(e) material

Record	Type	Message Sent Date/Time	Message	Sender / Author	Recipient(s)	ChatID	Attachments
Holmes_iPhone_iMessage-MMS-SMS_029913	iMessage	4/9/2015 9:08:58 PM	When we launch in NY we can launch with CVS and give them once we have 50 E done, we will be invincible	Sunny Balwani (	Elizabeth Holmes		
Holmes_iPhone_iMessage-MMS-SMS_029910	iMessage	4/9/2015 9:12:30 PM	Agree	Elizabeth Holmes	Sunny Balwani (		
Holmes_iPhone_iMessage-MMS-SMS_029917	iMessage	4/9/2015 9:14:22 PM	If terms because we term then we return. They term and we don't want to we keep.	Elizabeth Holmes	Sunny Balwani (		
Holmes_iPhone_iMessage-MMS-SMS_029918	iMessage	4/9/2015 9:14:45 PM	We don't want 1000 stores with ass holes.	Sunny Balwani (·	Elizabeth Holmes		
Holmes_iPhone_iMessage-MMS-SMS_029920	iMessage	4/9/2015 9:15:03 PM	200 will be enough to prove our point.	Sunny Balwani (·	Elizabeth Holmes		
Holmes_iPhone_iMessage-MMS-SMS_029922	iMessage	4/9/2015 9:15:06 PM	I know	Elizabeth Holmes	Sunny Balwani		
Holmes_iPhone_iMessage-MMS-SMS_029921	iMessage	4/9/2015 9:15:17 PM	I will say we keep 25 no matter what	Sunny Balwani (·)	Elizabeth Holmes		
Holmes_iPhone_iMessage-MMS-SMS_029919	iMessage	4/9/2015 9:15:19 PM	But then depending on who terms should work	Elizabeth Holmes	Sunny Balwani (		
Holmes_iPhone_iMessage-MMS-SMS_029923	iMessage	4/9/2015 9:15:22 PM	Agree	Elizabeth Holmes	Sunny Balwani (		
Holmes_iPhone_iMessage-MMS-SMS_029925	iMessage	4/9/2015 9:15:27 PM	Yes	Sunny Balwani (·	Elizabeth Holmes		
Holmes_iPhone_iMessage-MMS-SMS_029924	iMessage	4/9/2015 9:15:44 PM	But if natural terms then we return 25	Sunny Balwani (·	Elizabeth Holmes		
Holmes_iPhone_iMessage-MMS-SMS_029926	iMessage	4/9/2015 9:15:44 PM	If they don't build 500 we keep 25	Sunny Balwani (·	Elizabeth Holmes		
Holmes_iPhone_iMessage-MMS-SMS_029929	iMessage	4/9/2015 9:17:52 PM	Correct	Sunny Balwani (·	Elizabeth Holmes		
Holmes_iPhone_iMessage-MMS-SMS_029928	iMessage	4/9/2015 9:18:40 PM	Yes	Elizabeth Holmes	Sunny Balwani (		
Holmes_iPhone_iMessage-MMS-SMS_029930	iMessage	4/9/2015 9:19:05 PM	Natural meaning we both decide not to renew? Also if we want Renew but they don't	Elizabeth Holmes	Sunny Balwani (		
Holmes_iPhone_iMessage-MMS-SMS_029931	iMessage	4/9/2015 9:20:00 PM	I would like to keep simple. If they build minimum 500 they get all 50. If they don't we keep minimum 25. I can also say if they don't build 500 we keep all 50 since we banked on them.	Sunny Balwani (	Elizabeth Holmes		
Holmes_iPhone_iMessage-MMS-SMS_029940	iMessage	4/9/2015 10:28:16 PM	Going into wag meeting.	Sunny Balwani (	Elizabeth Holmes		
Holmes_iPhone_iMessage-MMS-SMS_029945	iMessage	4/10/2015 12:34:08 AM	Done. Call when u have 30 minutes	Sunny Balwani (	Elizabeth Holmes		
Holmes_iPhone_iMessage-MMS-SMS_029947	iMessage	4/10/2015 1:41:00 AM	Agree with above	Elizabeth Holmes	Sunny Balwani (		
Holmes_iPhone_iMessage-MMS-SMS_029949	iMessage	4/10/2015 1:41:03 AM	Will call soon	Elizabeth Holmes	Sunny Balwani (		
Holmes_iPhone_iMessage-MMS-SMS_029948	iMessage	4/10/2015 1:50:22 AM	Mostly terrible meeting but net net is what we want.	Sunny Balwani (·	Elizabeth Holmes		
Holmes_iPhone_iMessage-MMS-SMS_029972	iMessage	4/10/2015 2:33:36 AM	Love you too	Sunny Balwani (·	Elizabeth Holmes		
Holmes_iPhone_iMessage-MMS-SMS_029974	iMessage	4/10/2015 2:33:36 AM	The point about narrowing down menu to hit high fs % came to me like gift of God.	Sunny Balwani (·	Elizabeth Holmes		

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Record	Type	Message Sent Date/Time	Message	Sender / Author	Recipient(s)	ChatID	Attachments
Holmes_iPhone_iMessage-MMS-SMS_029975	iMessage	4/10/2015 2:35:44 AM	I was meditating on this meeting all night and all day	Sunny Balwani (	Elizabeth Holmes	4	
Holmes_iPhone_iMessage-MMS-SMS_029976	iMessage	4/10/2015 2:35:44 AM	You nailed it	Elizabeth Holmes	Sunny Balwani (	4	
Holmes_iPhone_iMessage-MMS-SMS_029979	iMessage	4/10/2015 2:35:44 AM	We must hit our volume goals now.	Sunny Balwani	Elizabeth Holmes	4	
Holmes_iPhone_iMessage-MMS-SMS_029980	iMessage	4/10/2015 2:35:44 AM	We need to make it a matter of life and death.	Sunny Balwani	Elizabeth Holmes	4	
Holmes_iPhone_iMessage-MMS-SMS_029982	iMessage	4/10/2015 2:35:44 AM	Survival. We must not lose	Sunny Balwani	Elizabeth Holmes	4	

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Record	Type	Message Sent Date/Time	Message	Sender / Author	Recipient(s)	ChatID	Attachments
Holmes_iPhone_iMessage-MMS-SMS_032380	iMessage	4/29/2015 7:33:14 PM	Btw I sent CVS document to heather and chris on Saturday and haven't received any feedback from them.	Sunny Balwani (	Elizabeth Holmes		
Holmes_iPhone_iMessage-MMS-SMS_032383	iMessage	4/29/2015 7:35:23 PM	Ok I will be there (landing in 2 hours 10 mins) and can meet with any candidates we think make sense. Nothing is on my calendar. Do you want me to email heather chris on turning the cvs document	Elizabeth Holmes	Sunny Balwani (		
Holmes_iPhone_iMessage-MMS-SMS_032382	iMessage	4/29/2015 7:35:28 PM	No	Sunny Balwani (	Elizabeth Holmes		
Holmes_iPhone_iMessage-MMS-SMS_032381	iMessage	4/29/2015 7:36:39 PM	Are they helping you on wag contract	Elizabeth Holmes	Sunny Balwani (		
Holmes_iPhone_iMessage-MMS-SMS_032384	iMessage	4/29/2015 7:37:23 PM	No one on wag contract being want anyone on wag contract. This u and I need close our chests.	Sunny Balwani (	Elizabeth Holmes		
Holmes_iPhone_iMessage-MMS-SMS_032385	iMessage	4/29/2015 7:37:32 PM	Don't want	Sunny Balwani (	Elizabeth Holmes		

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Fed. R. Crim. P. 6(e) material

Record	Type	Message Sent Date/Time	Message	Sender / Author	Recipient(s)	ChatID	Attachments
Holmes_iPhone_iMessage-MMS-SMS_033940	iMessage	5/12/2015 4:51:09 PM	I presented CA bye asked me why we wouldn't do CA with WAg "out of curiosity"	Sunny Balwani	Elizabeth Holmes		
Holmes_iPhone_iMessage-MMS-SMS_033941	iMessage	5/12/2015 4:51:12 PM	I told him cvs has better footprint in SoCal but walgreens is not too far behind	Sunny Balwani	Elizabeth Holmes		

Record	Type	Message Sent Date/Time	Message	Sender / Author	Recipient(s)	ChatID	Attachments
Holmes_iPhone_iMessage-MMS-SMS_033943	iMessage	5/12/2015 4:51:12 PM	Cvs won't happen for another year	Sunny Balwani (+	Elizabeth Holmes		
Holmes_iPhone_iMessage-MMS-SMS_033944	iMessage	5/12/2015 4:51:12 PM	So if they want then we will move without them.	Sunny Balwani (+	Elizabeth Holmes		
Holmes_iPhone_iMessage-MMS-SMS_033945	iMessage	5/12/2015 4:51:12 PM	We will talk about wag when u r back n	Sunny Balwani (+	Elizabeth Holmes		
Holmes_iPhone_iMessage-MMS-SMS_033946	iMessage	5/12/2015 4:51:12 PM	I sent u contract and cover note. Please spend time on that so I can send out	Sunny Balwani (+	Elizabeth Holmes		
Holmes_iPhone_iMessage-MMS-SMS_033939	iMessage	5/12/2015 4:51:29 PM	Hmm	Elizabeth Holmes	Sunny Balwani (		
Holmes_iPhone_iMessage-MMS-SMS_033942	iMessage	5/12/2015 4:51:50 PM	Yeah	Elizabeth Holmes	Sunny Balwani (		
Holmes_iPhone_iMessage-MMS-SMS_033948	iMessage	5/12/2015 4:54:44 PM	K	Elizabeth Holmes	Sunny Balwani (		
Holmes_iPhone_iMessage-MMS-SMS_033947	iMessage	5/12/2015 4:54:54 PM	What's your sense on why 12 mo for cvs	Elizabeth Holmes	Sunny Balwani (		
Holmes_iPhone_iMessage-MMS-SMS_033949	iMessage	5/12/2015 5:00:21 PM	/ where did u leave it w him	Elizabeth Holmes	Sunny Balwani (		
Holmes_iPhone_iMessage-MMS-SMS_033950	iMessage	5/12/2015 5:02:18 PM	They don't know the upside or downside of not having this.	Sunny Balwani (	Elizabeth Holmes		
Holmes_iPhone_iMessage-MMS-SMS_033951	iMessage	5/12/2015 5:02:29 PM	Yeah	Elizabeth Holmes	Sunny Balwani (		
Holmes_iPhone_iMessage-MMS-SMS_033954	iMessage	5/12/2015 5:02:42 PM	Was he upset abt missing pa	Elizabeth Holmes	Sunny Balwani (		
Holmes_iPhone_iMessage-MMS-SMS_033953	iMessage	5/12/2015 5:02:48 PM	And the fact we r not growing with wag is something they are trying to understand	Sunny Balwani (	Elizabeth Holmes		
Holmes_iPhone_iMessage-MMS-SMS_033952	iMessage	5/12/2015 5:04:41 PM	They are all lemmings. They only want if others want it	Sunny Balwani (	Elizabeth Holmes		
Holmes_iPhone_iMessage-MMS-SMS_033955	iMessage	5/12/2015 5:04:58 PM	Thinking	Elizabeth Holmes	Sunny Balwani (		
Holmes_iPhone_iMessage-MMS-SMS_033958	iMessage	5/12/2015 5:05:08 PM	The minute I said California his question was why cvs why not walgreens.	Sunny Balwani (-	Elizabeth Holmes		
Holmes_iPhone_iMessage-MMS-SMS_033959	iMessage	5/12/2015 5:05:14 PM	I know	Elizabeth Holmes	Sunny Balwani		
Holmes_iPhone_iMessage-MMS-SMS_033957	iMessage	5/12/2015 5:05:31 PM	Instead if Theranos was strategic to them he would have jumped on it	Sunny Balwani (	Elizabeth Holmes		
Holmes_iPhone_iMessage-MMS-SMS_033956	iMessage	5/12/2015 5:06:00 PM	Seeing our locations in pa will be the same reaction	Elizabeth Holmes	Sunny Balwani (		
Holmes_iPhone_iMessage-MMS-SMS_033960	iMessage	5/12/2015 5:06:08 PM	They don't think of us as strategic. Every conversation I have with him he spends at least half of it in when can we put devices in minute clinics.	Sunny Balwani (-	Elizabeth Holmes		
Holmes_iPhone_iMessage-MMS-SMS_033962	iMessage	5/12/2015 5:06:08 PM	Just like 3 years ago	Sunny Balwani (	Elizabeth Holmes		

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Record	Type	Message Sent Date/Time	Message	Sender / Author	Recipient(s)	ChatID	Attachments
Holmes_iPhone_iMessage-MMS-SMS_039927	iMessage	8/1/2015 3:22:40 AM	Highest volume day today. 547 in wag.	Sunny Balwani (+	Elizabeth Holmes		

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Fed. R. Crim. P. 6(e) material

Record	Type	Message Sent Date/Time	Message	Sender / Author	Recipient(s)	ChatID	Attachments
Holmes_iPhone_iMessage-MMS-SMS_045902	iMessage	10/15/2015 4:21:37 AM	Jc article is out.	Sunny Balwani	Elizabeth Holmes		

FOIA Confidential Treatment Requested by Theranos
Fed. R. Crim. P. 6(e) material

Record	Type	Message Sent Date/Time	Message	Sender / Author	Recipient(s)	ChatID	Attachments
Holmes_iPhone_iMessage-MMS-SMS_045965	iMessage	10/15/2015 10:30:12 AM	I am ok with less blood and discomfort in holding statement	Elizabeth Holmes	Sunny Balwani		
Holmes_iPhone_iMessage-MMS-SMS_045966	iMessage	10/15/2015 10:30:20 AM	Almost odd if not there	Elizabeth Holmes	Sunny Balwani		

FOIA Confidential Treatment Requested by Theranos
Fed. R. Crim. P. 6(e) material

Record	Type	Message Sent Date/Time	Message	Sender / Author	Recipient(s)	ChatID	Attachments
Holmes_iPhone_iMessage-MMS-SMS_045967	iMessage	10/15/2015 10:30:25 AM	Ok	Sunny Balwani (-	Elizabeth Holmes	-	
Holmes_iPhone_iMessage-MMS-SMS_045968	iMessage	10/15/2015 10:30:37 AM	Just worried about FDA and cms	Sunny Balwani (-	Elizabeth Holmes		
Holmes_iPhone_iMessage-MMS-SMS_045970	iMessage	10/15/2015 10:30:42 AM	But ok.	Sunny Balwani (-	Elizabeth Holmes	-	
Holmes_iPhone_iMessage-MMS-SMS_045969	iMessage	10/15/2015 10:30:47 AM	Have to take this risk	Sunny Balwani (-	Elizabeth Holmes	-	
Holmes_iPhone_iMessage-MMS-SMS_045971	iMessage	10/15/2015 10:32:12 AM	We made such big deal when they were here about venipuncture being less blood I am comfortable with it	Elizabeth Holmes	Sunny Balwani (-	-	
Holmes_iPhone_iMessage-MMS-SMS_045981	iMessage	10/15/2015 11:44:52 AM	Cramer wants exclusive	Elizabeth Holmes	Sunny Balwani I	-	
Holmes_iPhone_iMessage-MMS-SMS_045982	iMessage	10/15/2015 11:44:55 AM	No other tv	Elizabeth Holmes	Sunny Balwani I	-	
Holmes_iPhone_iMessage-MMS-SMS_045985	iMessage	10/15/2015 12:11:44 PM	Wait for David	Sunny Balwani I	Elizabeth Holmes	-	

FOIA Confidential Treatment Requested by Theranos
Fed. R. Crim. P. 6(e) material

Record	Type	Message Sent Date/Time	Message	Sender / Author	Recipient(s)	ChatID	Attachments
Holmes_iPhone_iMessage-MMS-SMS_046001	iMessage	10/16/2015 5:09:23 PM	Sending draft Rupert email. The language about what jC said is David's language dying	Elizabeth Holmes	Sunny Balwani		
Holmes_iPhone_iMessage-MMS-SMS_046002	iMessage	10/16/2015 5:09:24 PM	Fyi	Elizabeth Holmes	Sunny Balwani		
Holmes_iPhone_iMessage-MMS-SMS_046003	iMessage	10/16/2015 5:09:48 PM	Ok	Sunny Balwani	Elizabeth Holmes		
Holmes_iPhone_iMessage-MMS-SMS_046004	iMessage	10/16/2015 5:12:32 PM	Which part is David language	Sunny Balwani	Elizabeth Holmes		
Holmes_iPhone_iMessage-MMS-SMS_046007	iMessage	10/16/2015 5:23:56 PM	The part about why I didn't want to talk to JC (his accusations) as well as the other paragraphs that weren't there before. Everything new except the one sentence I added on the new article	Elizabeth Holmes	Sunny Balwani		
Holmes_iPhone_iMessage-MMS-SMS_046006	iMessage	10/16/2015 5:28:27 PM	I am comfortable with saying the death and sex thing to Rupert BC it makes the point	Elizabeth Holmes	Sunny Balwani (		
Holmes_iPhone_iMessage-MMS-SMS_046008	iMessage	10/16/2015 5:28:45 PM	Don't.	Sunny Balwani (	Elizabeth Holmes		
Holmes_iPhone_iMessage-MMS-SMS_046005	iMessage	10/16/2015 5:28:54 PM	Don't what	Elizabeth Holmes	Sunny Balwani (		
Holmes_iPhone_iMessage-MMS-SMS_046009	iMessage	10/16/2015 5:29:11 PM	Don't make the death and sex point. Not ok	Sunny Balwani (	Elizabeth Holmes		
Holmes_iPhone_iMessage-MMS-SMS_046010	iMessage	10/16/2015 5:29:55 PM	Challenge is you saw how everyone reacted in press to me not meeting with him	Elizabeth Holmes	Sunny Balwani (		
Holmes_iPhone_iMessage-MMS-SMS_046012	iMessage	10/16/2015 5:30:19 PM	They didn't think him challenging me on patents was remotely a good reason not to meet w him	Elizabeth Holmes	Sunny Balwani		
Holmes_iPhone_iMessage-MMS-SMS_046013	iMessage	10/16/2015 5:31:29 PM	But we have enuff points to say I didn't meet with him because of his false accusations and didn't have to meet with someone who was attacking me without even meeting with me. For example patents.	Sunny Balwani (	Elizabeth Holmes		
Holmes_iPhone_iMessage-MMS-SMS_046011	iMessage	10/16/2015 5:31:44 PM	I wouldn't open up use personal life or murder because enough people on Twitter will assume there is something there.	Sunny Balwani	Elizabeth Holmes		
Holmes_iPhone_iMessage-MMS-SMS_046016	iMessage	10/16/2015 5:31:44 PM	It's filth	Sunny Balwani	Elizabeth Holmes		
Holmes_iPhone_iMessage-MMS-SMS_046017	iMessage	10/16/2015 5:31:44 PM	And we need to get out of flirty	Sunny Balwani	Elizabeth Holmes		
Holmes_iPhone_iMessage-MMS-SMS_046015	iMessage	10/16/2015 5:32:22 PM	Filth	Sunny Balwani	Elizabeth Holmes		
Holmes_iPhone_iMessage-MMS-SMS_046014	iMessage	10/16/2015 5:32:46 PM	Agree for sure on outside world. Even w Rupert to make point?	Elizabeth Holmes	Sunny Balwani (		
Holmes_iPhone_iMessage-MMS-SMS_046018	iMessage	10/16/2015 5:33:29 PM	If u feel strongly about murder. But not personal life.	Sunny Balwani (	Elizabeth Holmes		
Holmes_iPhone_iMessage-MMS-SMS_046020	iMessage	10/16/2015 5:35:55 PM	I think it is important to send this email but doesn't help with public beating. All our partners are bailing one at a time and same with investors.	Sunny Balwani (	Elizabeth Holmes		

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Record	Type	Message Sent Date/Time	Message	Sender / Author	Recipient(s)	ChatID	Attachments
Holmes_iPhone_iMessage-MMS-SMS_046025	iMessage	10/16/2015 5:37:57 PM	Dignity wag everyone is posturing to walk away. We r losing leverage fast	Sunny Balwani	Elizabeth Holmes		
Holmes_iPhone_iMessage-MMS-SMS_046023	iMessage	10/16/2015 5:38:45 PM	Have you talked to wag	Elizabeth Holmes	Sunny Balwani		
Holmes_iPhone_iMessage-MMS-SMS_046028	iMessage	10/16/2015 5:39:17 PM	They r not talking for now until their lawyers say so	Sunny Balwani	Elizabeth Holmes		
Holmes_iPhone_iMessage-MMS-SMS_046029	iMessage	10/16/2015 5:39:28 PM	To us?	Elizabeth Holmes	Sunny Balwani		
Holmes_iPhone_iMessage-MMS-SMS_046031	iMessage	10/16/2015 5:39:33 PM	Yes	Sunny Balwani	Elizabeth Holmes		
Holmes_iPhone_iMessage-MMS-SMS_046030	iMessage	10/16/2015 5:39:38 PM	At c level	Sunny Balwani	Elizabeth Holmes		
Holmes_iPhone_iMessage-MMS-SMS_046032	iMessage	10/16/2015 5:39:49 PM	Their lawyers told them not to talk to us?	Elizabeth Holmes	Sunny Balwani		
Holmes_iPhone_iMessage-MMS-SMS_046033	iMessage	10/16/2015 5:39:53 PM	Yes	Sunny Balwani	Elizabeth Holmes		
Holmes_iPhone_iMessage-MMS-SMS_046034	iMessage	10/16/2015 5:39:57 PM	Wow	Elizabeth Holmes	Sunny Balwani		
Holmes_iPhone_iMessage-MMS-SMS_046035	iMessage	10/16/2015 5:40:01 PM	In so many words	Sunny Balwani	Elizabeth Holmes		
Holmes_iPhone_iMessage-MMS-SMS_046036	iMessage	10/16/2015 5:40:16 PM	Not exactly but they will bring all this up about finger sticks etc in contract negotiations	Sunny Balwani	Elizabeth Holmes		
Holmes_iPhone_iMessage-MMS-SMS_046044	iMessage	10/16/2015 5:41:47 PM	It is going to be very difficult 12 months.	Sunny Balwani	Elizabeth Holmes		
Holmes_iPhone_iMessage-MMS-SMS_046043	iMessage	10/16/2015 5:42:24 PM	Our CLIA lab failed mpv pt all 5 levels. Just found out. Dealing with it.	Sunny Balwani	Elizabeth Holmes		

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Record	Type	Message Sent Date/Time	Message	Sender / Author	Recipient(s)	ChatID	Attachments
Holmes_iPhone_iMessage-MMS-SMS_046058	iMessage	10/16/2015 5:48:48 PM	Miss old days. These days are not worth whatever we r trying to do here	Sunny Balwani	Elizabeth Holmes		
Holmes_iPhone_iMessage-MMS-SMS_046061	iMessage	10/16/2015 5:53:04 PM	Nim just texted me. Wants to talk urgently	Sunny Balwani	Elizabeth Holmes		
Holmes_iPhone_iMessage-MMS-SMS_046066	iMessage	10/16/2015 6:00:38 PM	U calling nim?	Elizabeth Holmes	Sunny Balwani		
Holmes_iPhone_iMessage-MMS-SMS_046068	iMessage	10/16/2015 6:00:54 PM	He will call me when ready	Sunny Balwani	Elizabeth Holmes		
Holmes_iPhone_iMessage-MMS-SMS_046067	iMessage	10/16/2015 6:01:22 PM	Let me know how it goes. The facts are on our side.	Elizabeth Holmes	Sunny Balwan		
Holmes_iPhone_iMessage-MMS-SMS_046071	iMessage	10/16/2015 6:01:36 PM	I know. I am strong on facts. They always react to anything but I will be strong.	Sunny Balwani	Elizabeth Holmes		

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Fed. R. Crim. P. 6(e) material

Record	Type	Message Sent Date/Time	Message	Sender / Author	Recipient(s)	ChatID	Attachments
Holmes_iPhone_iMessage-MMS-SMS_046098	iMessage	10/16/2015 7:26:56 PM	Ok. Wag freaking out. Lack of transparency	Sunny Balwani (	Elizabeth Holmes		
Holmes_iPhone_iMessage-MMS-SMS_046099	iMessage	10/16/2015 7:26:56 PM	Why they found this all out thru media and not thru us	Sunny Balwani (	Elizabeth Holmes		
Holmes_iPhone_iMessage-MMS-SMS_046096	iMessage	10/16/2015 7:28:11 PM	K that's what we'll do	Elizabeth Holmes	Sunny Balwani		
Holmes_iPhone_iMessage-MMS-SMS_046097	iMessage	10/16/2015 7:28:18 PM	How was Nim	Elizabeth Holmes	Sunny Balwani I		
Holmes_iPhone_iMessage-MMS-SMS_046100	iMessage	10/16/2015 7:29:20 PM	Why we didn't tel them about turning off nanotainer a	Sunny Balwani I	Elizabeth Holmes		
Holmes_iPhone_iMessage-MMS-SMS_046101	iMessage	10/16/2015 7:29:28 PM	Did you tell him it literally just happened	Elizabeth Holmes	Sunny Balwani I		
Holmes_iPhone_iMessage-MMS-SMS_046103	iMessage	10/16/2015 7:29:32 PM	Yes	Sunny Balwani I	Elizabeth Holmes		
Holmes_iPhone_iMessage-MMS-SMS_046104	iMessage	10/16/2015 7:29:40 PM	And we hadn't finalized plan w Fda yet and still haven't	Elizabeth Holmes	Sunny Balwani (		
Holmes_iPhone_iMessage-MMS-SMS_046102	iMessage	10/16/2015 7:29:53 PM	I told him we were surprised by the article as much as they r	Sunny Balwani I	Elizabeth Holmes		
Holmes_iPhone_iMessage-MMS-SMS_046105	iMessage	10/16/2015 7:30:00 PM	Yes	Sunny Balwani I	Elizabeth Holmes		
Holmes_iPhone_iMessage-MMS-SMS_046109	iMessage	10/16/2015 7:30:29 PM	But it was matter of communication. I had actually thought about it but got too busy to chat with u	Sunny Balwani I	Elizabeth Holmes		
Holmes_iPhone_iMessage-MMS-SMS_046107	iMessage	10/16/2015 7:31:12 PM	Then let's show them that this literally is still up in air so we literally just decided since the discussion is getting aired out in press	Elizabeth Holmes	Sunny Balwani		
Holmes_iPhone_iMessage-MMS-SMS_046108	iMessage	10/16/2015 7:32:09 PM	Ok	Sunny Balwani (	Elizabeth Holmes		
Holmes_iPhone_iMessage-MMS-SMS_046106	iMessage	10/16/2015 7:32:31 PM	However issue is we didn't tel them In advance about switching	Sunny Balwani (	Elizabeth Holmes		
Holmes_iPhone_iMessage-MMS-SMS_046110	iMessage	10/16/2015 7:32:56 PM	We'll have to present well that we hadn't decided to	Elizabeth Holmes	Sunny Balwani (		
Holmes_iPhone_iMessage-MMS-SMS_046113	iMessage	10/16/2015 7:33:20 PM	Bad idea. At this point they know. So need to be transparent.	Sunny Balwani (-	Elizabeth Holmes		
Holmes_iPhone_iMessage-MMS-SMS_046114	iMessage	10/16/2015 7:35:27 PM	How long has it been that we didn't tell them	Elizabeth Holmes	Sunny Balwani I		
Holmes_iPhone_iMessage-MMS-SMS_046112	iMessage	10/16/2015 7:35:28 PM	3-4weeks.	Sunny Balwani (	Elizabeth Holmes		
Holmes_iPhone_iMessage-MMS-SMS_046111	iMessage	10/16/2015 7:42:33 PM	I'm trying to remember what our thinking was on that	Elizabeth Holmes	Sunny Balwani I		
Holmes_iPhone_iMessage-MMS-SMS_046115	iMessage	10/16/2015 7:43:03 PM	None. We just didn't tell them thinking under new model this doesn't matter.	Sunny Balwani I	Elizabeth Holmes		
Holmes_iPhone_iMessage-MMS-SMS_046117	iMessage	10/16/2015 7:43:23 PM	But attacks like this scare them as they scare everyone.	Sunny Balwani I	Elizabeth Holmes		
Holmes_iPhone_iMessage-MMS-SMS_046118	iMessage	10/16/2015 7:46:32 PM	Yeah.	Elizabeth Holmes	Sunny Balwani		

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EXHIBIT 32

theranos

1701 Page Mill Road
Palo Alto, CA 94304

P 650.838.9292
F 650.838.9165

theranos.com

February 12, 2016

BY MESSENGER

Ms. Karen Fuller
State Oversight and CLIA Branch
Division of Survey and Certification
Centers for Medicare and Medicaid Services
90 7th Street, Suite 5-300 (5W)
San Francisco, CA 94103-6707

Re: Allegation of Compliance and Evidence of Correction, Form CMS-2567 (CLIA Number 05D2025714)

Dear Ms. Fuller:

I write to provide you with Theranos, Inc.'s allegation of compliance and evidence of correction in response to the Statement of Deficiencies ("Plan of Correction"), Form CMS-2567, received by Theranos on January 26, 2016.

Please note that the Plan of Correction, like the Statement of Deficiencies, contains highly sensitive trade secret and confidential commercial information that Theranos has submitted and is submitting to CMS solely in connection with its survey. Public release of this information would irreparably harm Theranos' proprietary and business interests. As such, this information is exempt from disclosure under the Freedom of Information Act ("FOIA")[1] and CMS regulations.[2]

We respectfully request that you refrain from producing any copies of Theranos' Plan of Correction, the Statement of Deficiencies, or any exhibits or documents related thereto, redacted or otherwise, to any member of the public at this time. We are preparing a request for certain redactions to the Plan of Correction, which we will provide to you in the coming days. These redactions will supplement our requested redactions to the Statement of Deficiencies, which I submitted to you on February 4, 2016.

In addition, I hereby request sufficient advance notice prior to public disclosure of any of these documents.

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[1] *See* 5 U.S.C. § 552(b)(4) (exempting "trade secrets and commercial or financial information obtained from a person and privileged or confidential" from public disclosure).

[2] *See* 42 C.F.R. § 401.116 ("CMS will, upon request made in accordance with this subpart, make identified records available to any person, unless they are exempt from disclosure under the provisions of section 552(b) of title 5."); *id.* § 401.126(a) ("Pursuant to paragraph (b) of 5 U.S.C. 552, certain classes of records are exempt from disclosure. For some examples of the kinds of materials which are exempt, see subpart F of the public information regulation of the Department of Health and Human Services (45 CFR part 5) and the appendix to that regulation."); *see also* 45 C.F.R. part 5, subpart F, § 5.65 ("We will withhold trade secrets and commercial or financial information that is obtained from a person and is privileged or confidential.").

Confidential

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Finally, if CMS determines to transfer any of Theranos' confidential material to another federal agency, please forward a copy of this letter to that agency along with any confidential material and indicate that Theranos has requested confidential treatment of the material.

I am available to address any questions and look forward to continuing our work together.

Sincerely,

Heather King
General Counsel

cc: Gary Yamamoto
Sarah Bennett

Enclosures

Confidential

CONFIDENTIAL COMMERCIAL INFORMATION EXEMPT FROM DISCLOSURE UNDER THE FREEDOM OF INFORMATION ACT

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

PRINTED: 01/25/2016
FORM APPROVED
OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	05D2025714	A. BUILDING _____ B. WING _____	11/20/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
THERANOS INC	7333 GATEWAY BLVD NEWARK, CA 94560

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
D2094	493.841(e) ROUTINE CHEMISTRY (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) documentation and interview with the General Supervisor (GS), the laboratory failed to investigate and document the investation of ungraded alkaline phosphatase (ALP) PT results for the 3rd event of 2014. Findings include: a. The laboratory was enrolled with the College of American Pathologists (CAP) PT program for ALP for the 3rd event 2014. b. The CAP results showed that five of five samples (CHM-06 through CHM-10) were ungraded with a code [20]. c. There was no documenation that the ungraded ALP results had been investigated. d. The general supervisor stated that the Quality Control/Quality Assurance (QC/QA) Manager was responsible for investigating ungraded PT results. e. The QC/QA Manger confirmed on 11/18/15 that an investigation was not done or	D2094	D2094 The lab has investigated this ungraded PT event for ALP and has documented its investigation and conclusions. The new lab director has approved enhanced procedures for proficiency testing, which reinforce the lab's systems for the investigation of ungraded PT results. The lab's technical supervisors will be responsible for ensuring that these procedures are implemented and followed. The lab will provide oversight through monthly QA meetings by reviewing investigations and corrective action for ungraded proficiency tests with outcomes of less than 100%. In addition, the lab will monitor compliance through its improved occurrence management, and audit procedures.	2/12/16

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE: Kingshuk Das
Digitally signed by Kingshuk Das
Date: 2016.02.12 10:18:05 -08'00'

TITLE: Lab Director

(X6) DATE: 2/12/16

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. (See instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

CONFIDENTIAL COMMERCIAL INFORMATION EXEMPT FROM DISCLOSURE UNDER THE FREEDOM OF INFORMATION ACT

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	05D2025714	A. BUILDING _____ B. WING _____	11/20/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
THERANOS INC	7333 GATEWAY BLVD NEWARK, CA 94560

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
D5805	Continued From page 70 (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of final reports and interview with the Senior Vice President, the laboratory failed to differentiate the intrepretive data for Warfarin therapy vs. Non-Warfarin Therapy. Findings include: a. Thirteen of thirteen final patient test reports reviewed indicated that the International Normalized Ratio (INR) interpretive data on the final report was identical for Warfarin therapy and non-Warfarin therapy. b. The Senior Vice President confirmed the above finding on 9/22/15 at approximately 4:45 pm.	D5805	D5805 (continued): The lab has completed an assessment to identify any patients affected or having the potential to be affected by this issue. The new lab director has approved enhanced reporting procedures that require the technical supervisor to verify that interpretive information is accurate and to obtain approval from the lab director or clinical consultant before any updates are implemented. The lab will provide oversight through monthly QA meetings, and will also monitor compliance through its improved occurrence management, and audit procedures.	
D5821	493.1291(k) TEST REPORT When errors in the reported patient test results are detected, the laboratory must do the following: (k)(1) Promptly notify the authorized person ordering the test and, if applicable, the individual using the test results of reporting errors. (k)(2) Issue corrected reports promptly to the authorized person ordering the test and, if applicable, the individual using the test results. (k)(3) Maintain duplicates of the original report, as	D5821	D5821: The new lab director has approved enhanced procedures to address correcting potential errors in patient reports. These procedures require that the person ordering the test is promptly notified after the lab determines that a correction is required.	2/12/16

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	05D2025714	A. BUILDING _____ B. WING _____	11/20/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
THERANOS INC	7333 GATEWAY BLVD NEWARK, CA 94560

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
D5821	Continued From page 71 well as the corrected report. This STANDARD is not met as evidenced by: Based on review of patient test reports and interview with the technical supervisor, the laboratory failed to notify the authorized person for approximately seven weeks after the surveyor identified a quality control problem with Prothrombin Time/International Normalized Ratio (PT/INR). Findings include: a. Refer to D6093. b. Five of thirteen final patient reports reviewed showed corrected reports were faxed between 11/11/15 and 11/15/15. c. Eight of thirteen final patient reports reviewed did not show documentation that the authroized person was notified when an error in patient test results was detected. d. 81 PT/INR patient test results were reported from 4/1/15 through 9/16/15. e. The technical supervisor stated that all authorized persons were notified of the error in PT/INR results, including those without documentation.	D5821	D5821 (continued): The lab has completed an assessment to identify any patients affected or having the potential to be affected by this issue. The lab will provide oversight through monthly QA meetings, and will also monitor compliance through its improved occurrence management and audit procedures.	
D6076	493.1441 LABORATORY DIRECTOR The laboratory must have a director who meets the qualification requirements of §493.1443 of this subpart and provides overall management and direction in accordance with §493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on the number and severity of the	D6076	D6076: The laboratory has completed assessments to identify any patients affected or having the potential to be affected by the issues identified in this observation, and has taken corrective and preventative action. Among other things, the lab has hired a new lab	2/12/16

EXHIBIT 33

Table of Contents

Binder Letter	Volume Number	Tab	Summary
AA	1	1	D5311: Specimen Labeling
AA	1	2	D5400 and D5423: ALP Negative PT Bias 2015
AA	1	3	D5403, D5481 Finding #2, D5791 Finding #2, D5791 Finding #3, D6102, and D6115: TPS 3.5 (Edison)
AA	1	4	D5413 Finding #1 and D5791 Finding #1: Freezer Temperature
AA	1	5	D5421 Finding #2 and D5423: Clarifying "normal patient distribution"
AA	1	6	D5423: AMR for ALP
AA	1	7	D5481 Finding #1, D5801, D6093 Finding #2: PT/INR on BCS XP
AA	1	8	D5791 Finding #1 and D5793 Finding #3: HCG on Immulite
AA	1	9	D5791 Finding #1 and D5793 Finding #4: Anti-HBs on Immulite
AA	1	10	D5793 Finding #5: LH Assessment
AA	1	11	D5793 Finding #8: 10x Rule
AA	1	12	D6102: Personnel Training and Competency Files (TP6, TP11, TP31)
AA	1	13	D2094: Alkaline Phosphatase on Siemens Advia 1800

CONFIDENTIAL COMMERCIAL INFORMATION EXEMPT FROM DISCLOSURE UNDER THE FREEDOM OF INFORMATION ACT
Theranos Internal Only

Trial Exh. 4943 Page 0001
CMS2-164332
Case 5:18-cr-00258-EJD Document 1157 Filed 11/19/21 Page 324 of 393

CONFIDENTIAL COMMERCIAL INFORMATION EXEMPT FROM DISCLOSURE UNDER THE FREEDOM OF INFORMATION ACT

Patient Impact Assessment: TPS 3.5

DEFICIENCIES:

D5403 Finding #2, D5481 Finding #2, D5791 Finding #2, D5791 Finding #3, D6102, D6115

INVESTIGATION:

The laboratory agrees that its descriptions of prior analyses were lacking sufficient detail to explain the conclusions submitted in its original response.

Upon a review of that response, including the entirety of the prior analysis of TPS 3.5 QC data and patient test result distributions for all analytes during the time period examined, the laboratory made note of poor QC performance throughout. Therefore, the laboratory conducted an expanded retrospective analysis for 2014 and 2015 QC data. This data is presented at Ex. FF, Tabs 1-12. The laboratory noted multiple and recurrent time periods (across all analytes tested) of abrupt shifts in QC target means, high rates of 1-2s QC rule failures, and QC CVs far exceeding limits for a stable testing process.

PATIENT IMPACT:

Although the magnitude of QC deviations from target means does not necessarily reflect the exact nature and magnitude of bias on patient results because of differences in matrices, the QC failures identified by this comprehensive retrospective analysis reflect a global and long-term failure of the quality control program for this instrument, as well as failures of related quality assurance procedures that should have alerted the laboratory to correct such an unstable process. Therefore, the laboratory has concluded that there is a possible patient impact for every test reported from the laboratory's TPS 3.5 instruments.

CORRECTIVE ACTION:

The fraction of patient results truly impacted, and the nature and magnitude of any effect, are unknown. Out of an abundance of caution, the laboratory has voided all patient test results reported from the TPS 3.5 instruments. Many corrected reports have been transmitted, and the remainder are being transmitted. (Ex. KK). Transmission will be complete by March 31, 2016. The remainder of the transmittals and confirmations of receipt will be provided to CMS under separate cover.

CONFIDENTIAL COMMERCIAL INFORMATION EXEMPT FROM DISCLOSURE UNDER THE FREEDOM OF INFORMATION ACT

Trial Exh. 4943 Page 0009

CMS2-164340

EXHIBIT 34

IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN JOSE DIVISION

CERTIFIED COPY

SECURITIES AND EXCHANGE COMMISSION,
Plaintiff,
vs.
RAMESH "SUNNY" BALWANI,
Defendant.

CASE NO:
5:18-cv-01603-EJD

CONFIDENTIAL UNDER THE PROTECTIVE ORDER
VIDEOTAPED DEPOSITION OF GARY YAMAMOTO
FRIDAY, DECEMBER 6, 2019, 9:28 A.M.
SAN FRANCISCO, CALIFORNIA

Reported By: JoAnne T. Ichiki, CSR No. 11660
CLS Job No. 115879

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IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN JOSE DIVISION

SECURITIES AND EXCHANGE COMMISSION,
Plaintiff,
vs.
RAMESH "SUNNY" BALWANI,
Defendant.

CASE NO:
5:18-cv-01603-EJD

THE VIDEOTAPED DEPOSITION Of GARY YAMAMOTO, taken at The Orrick Building, 405 Howard Street, San Francisco, California 94105, on Friday, December 6, 2019, at 9:28 a.m. before JoAnne T. Ichiki, Certified Shorthand Reporter, in and for the State of California.

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A. Yeah, I don't recall.
Q. Okay.
A. Or I don't recall when.
Q. But was the subject matter relating to the possible voiding of tests run on the Edison?
A. I know that there was a conversation -- or there was information provided that voiding test results, you know, that the lab was thinking about voiding test results. Whether it was related specifically to the Edison or not, I don't recall.
Q. Was the voiding of tests something that CMS was requesting or requiring?
A. No.
Q. When you learned that the company was considering voiding tests, did that surprise you in any way?
A. Yeah, it's unusual. It's an unusual remediation for deficient practices.
Q. Why?
A. Well, I think given the scope and the numbers, number one, of test results would need to be voided as opposed to -- generally we would see laboratories contacting their clients and -- to let them know that there may have been issues with their test -- the test results during that period

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of time and that they may want to get retested.
That tends to be more -- a more typical scenario of what would happen.
Q. Is that different than voiding a test?
MR. HEFTY: Objection. Vague.
THE WITNESS: Voiding a test is not, I think, disclosing that there may have been a problem. I think there may be an inference by voiding a test that there was a problem. But, you know, it would be an inference, I think. I think there would be a difference.
BY MR. CAZARES:
Q. So the second round, I'll call it, of the survey came up in November. Yourself and Ms. Bennett returned.
Was there anyone else with you?
A. A few days, my manager, Karen Fuller, wanted to accompany us to kind of -- at that point there was a lot of media attention. She wanted to kind of get a sense of what the surveys were like.
Q. Okay. And on the Theranos side, Mr. Balwani was present again for the interaction?
A. Yes.
Q. And Ms. Holmes?
A. Yes.

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Q. And others on the Theranos side?
A. And others.
Q. What is your recollection as to others?
A. There were a lot of others. There were not only people that we had interacted with in the prior week in September, but there were several folks that were introduced to us as consultants.
Q. These were attorneys or lab people?
A. Laboratory consultants as well as -- there were attorneys there as well.
Q. Okay. And so what happened on the first day of the kind of second round of surveys?
A. I think we kind of asked if -- is there anything we need to discuss? And I think, you know, Sarah had issues with documents, I believe, and -- but we just kind of started where we left off in September.
Q. And did the company present you with documents or other information in an effort to address some of the issues that had been raised in September?
MR. HEFTY: Objection. Leading.
THE WITNESS: I don't remember that happening. I don't -- I don't know.
BY MR. CAZARES:

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Q. Was a presentation made on the second round of the survey in a similar way that happened in the first --
MR. HEFTY: Objection.
BY MR. CAZARES:
Q. -- in September?
MR. HEFTY: Sorry. Objection. Leading.
THE WITNESS: I don't think so. I don't recall that a presentation was made in the second week.
BY MR. CAZARES:
Q. And did you continue to engage in this kind of request for documentation and information from the lab personnel as you described took place in the September round of the survey?
MR. HEFTY: Objection. Leading.
THE WITNESS: Even more so in that we were getting more into the different analytic processes that would require me to look at more documents.
You know, Sarah conveyed to me that she was frustrated in the amount of time it was taking to get documents. Quite honestly, it wasn't so much my experience in that first week. I did -- many documents were available. But I did

REPORTER'S CERTIFICATION

I, JoAnne Ichiki, duly authorized to administer oaths pursuant to Section 2093(b) of the California Code of Civil Procedure, do hereby certify:

That the foregoing witness was by me administered an oath; that the deposition was then taken before me at the time and place herein set forth; that the testimony and proceedings were reported stenographically by me and later transcribed into typewriting under my direction; that the foregoing is a true record of the testimony and proceedings taken at that time.

Further, that if the foregoing pertains to the original transcript of a deposition in a Federal Case, before completion of the proceedings, review of the transcript (X) was ( ) was not requested.

I further certify that I am neither financially interested in the action nor a relative or employee of any attorney or party to this action

IN WITNESS WHEREOF, I have this date subscribed my name.

Dated: December 9, 2019

JOANNE ICHIKI

CSR NO. 11660

EXHIBIT 35

Page 1

UNITED STATES DISTRICT COURT

FOR THE

NORTHERN DISTRICT OF CALIFORNIA

SECURITIES AND EXCHANGE
COMMISSION,

CERTIFIED COPY

Plaintiff,

vs. CASE NO. 5:18-CV-01603-EJD

RAMESH "SUNNY" BALWANI,

Defendant.

_____/

CONFIDENTIAL PURSUANT TO PROTECTIVE ORDER

The above-captioned video deposition of SARAH BENNETT was held on Wednesday, January 29, 2020, commencing at 8:35 a.m., at the Law Offices of DLA Piper, 100 Light Street, Suite 1350, Baltimore, Maryland, before Steven Poulakos, Notary Public.

REPORTED BY: Steven Poulakos, RPR

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Page 4

APPEARANCES (Continued):

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ALSO PRESENT: RAMESH "SUNNY" BALWANI
IOANNIS ARSENIS, THE VIDEOGRAPHER

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BY MR. CAZARES:
Q What I'm trying to get at is the portion of the letter that is providing guidance relating to a credible allegation of compliance uses the word affect by the deficient practice.
A Right.
Q I'm trying to get some sort of clarification of what it means for a patient to be affected by a deficient practice.
A And that would be the determination of the laboratory director has to determine if and how any patients were affected by the deficient practice.
Q And does that mean that CMS surveyors do not themselves make a determination of if or how a patient may have been affected by a deficient practice?
A We do not know as CMS surveyors if patients were actually affected or not.
Q Thank you.
Now, point 2 continuing with the letter of that same passage, the letter indicates how the laboratory -- again, in addition, acceptable evidence of correction must include, 2, how the laboratory has identified other patients having the potential to be affected by the same deficient practice and what corrective actions has been -- what corrective action

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or actions has been taken.
Do you see that?
A I do.
Q I only have a question -- my question relates to the use of the phrase corrective actions in both one and two. What does that mean for a lab to have taken corrective actions relating to patients affected or potentially to be affected by noncompliance?
MR. KATZ: Objection, vague.
THE WITNESS: Again, CMS does not determine what those corrective actions must be. It's the laboratory and the laboratory director's responsibility to determine how those patients were affected or have been affected by the deficient practice and what they believe the corrective action should be.
BY MR. CAZARES:
Q What -- what would happen in a scenario where a lab was unable to determine how many patients may have been affected by noncompliance?
MR. KATZ: Objection, calls for speculation and incomplete hypothetical.
BY MR. CAZARES:
Q What would CMS and CLIA require under those circumstances?

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A I can't really speak to what CMS would require. And it was -- it was an issue in this particular case because CMS could never determine the entire universe of patients affected or potentially affected based on the information that we were provided.
Q And so what does that mean with respect to corrective actions?
MR. KATZ: Objection, vague.
THE WITNESS: Corrective actions is different than the universe of patients affected or potentially affected. It -- our requirement is that the laboratory identify any patients who were or potentially affected by a deficient practice and take corrective action. The onus is on the laboratory to find the entire universe of those patients.
BY MR. CAZARES:
Q With respect to patients who potentially may have been affected, what sort of corrective actions do laboratories take under those circumstances?
MR. KATZ: Objection, vague.
THE WITNESS: I can't speak to what corrective actions laboratory takes because that's their determination.
BY MR. CAZARES:

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Q In your experience having surveyed laboratories for the State of Maryland as well as CMS, have you ever experienced or observed corrective actions by a laboratory relating to patients who potentially may have been affected by noncompliance?
A Yes.
Q How many times?
A I can't give you a number.
Q More than one?
A Yes.
Q And what sort of corrective actions or attempts at corrective action were taken by those labs without identifying the specific labs because I don't need that?
A A laboratory could potentially use their -- their list of patients that were tested on a particular device and look at quality control. They could look at proficiency testing. They could look at other information related to the testing to see if there were any problems. They could pull patient histories or charts and compare results to the patient's history. There's a lot of things. Again, we're not prescriptive.
Q But what happens in the next step to the extent the surveyor has identified a deficiency and the

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laboratory has identified patients affected and patients who potentially have been affected? What's the lab supposed to do at that point?

MR. KATZ: Objection, vague and ambiguous.

THE WITNESS: We expect the laboratory to take corrective action if corrective action is warranted.

BY MR. CAZARES:

Q What sort of corrective actions? What are some examples?

A In my experience, they can notify the patient that there may have been a problem with a testing and that they need to have it retested and in other instances, they may not do anything.

Q Thank you.

You can turn the page on that. The letter is signed by -- appears to be signed by Karen Fuller. Was she the supervisor of Gary Yamamoto in --

A That's my understanding, yes.

Q Okay. And setting aside other -- other than in the circumstance of Theranos, have you previously had experience working with or alongside Karen Fuller?

A I have worked with her, yes.

Q And have you developed any -- any views as

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to Ms. Fuller's competency at her job?

A I would consider her to be competent.

Q Highly skilled?

MR. KATZ: Objection, vague.

THE WITNESS: I'm not quite sure what you mean by highly skilled.

BY MR. CAZARES:

Q Do you think she's good at her job?

A I believe so.

Q Thank you.

Turning to -- continuing on with the same exhibit. Behind the letter, there's the long document dated 11/20/2015. Is this the 2567 survey report?

Bless you.

A Thank you. Yes.

Q Okay. And what role, if any, did you have in the drafting of the 2567 attached to Exhibit 262?

A Any of the deficiencies that I cited on the 2567 were written by me.

Q And does that mean the rest would have been drafted by Mr. Yamamoto?

A Yes.

Q Now, focusing your attention on page 10812. We're not going to go through all of this, but there's some portions. 10182 in the lower right-hand corner.

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Do you see that page?

A I do.

Q Okay. And on the left-hand side near the top, there's a ID prefix tag D2128 next to that, some numbers in hematology.

Do you see that?

A Yes, I do.

Q What is that indicating?

A The 2128?

Q Yes.

A That's the deficiency tag.

Q And what's a deficiency tag?

A That's the tag that is related to the regulatory requirement at 493.8 51E. That's an administrative number that's used.

Q And this indicated here D2128 relates to hematology?

A Correct.

Q And did you contribute to or draft this portion of the 2567?

A Yes.

Q And did you draft all of it?

A Yes. That's --

MR. KATZ: Objection, vague.

THE WITNESS: For DTAG 2128, I believe I

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was the author of that DTAG.

BY MR. CAZARES:

Q And then if you continue to the next page 10813 after D2128, there's D5024.

A Yes.

Q Is that also your work?

A That is a combination of both Mr. Yamamoto and myself.

Q Now, under both of these -- under both of these DTAGs D2128 and D25024, D2128 is indicated as a standard level deficiency.

Do I have that right?

A Yes.

Q And what does that mean to be a standard level deficiency?

A We have two -- we have two levels of deficiency, standard and conditions. If you kind of think of it as a tree, the condition is the top of the tree and the standards are the limb under the tree. So they're standards that are wrapped up into a condition. Condition-level noncompliance is usually more serious than standard level.

Q And how do you decide what or how much evidence to cite in support of the deficiency finding?

MR. KATZ: Objection, vague.

ERRATA SHEET

Case: SEC V Ramesh "Sunny" Balwani

Witness: Sarah Bennett Date: 01/29/2020

PAGE/LINE	SHOULD READ	REASON FOR CHANGE

REPORTER'S CERTIFICATION

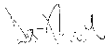
I, Steven Poulakos, Certified Shorthand Reporter in and for the State of Maryland, do hereby certify:

That the foregoing witness was by me duly sworn; that the deposition was then taken before me at the time and place herein set forth; that the testimony and proceedings were reported stenographically by me and later transcribed into typewriting under my direction; that the foregoing is a true record of the testimony and proceedings taken at that time.

I further certify that pursuant to FRCP Rule 30(e)(1), before completion of the deposition, review of the transcript [x] was [ ] was not requested.

I further certify I am neither financially interested in the action nor a relative or employee of any attorney or party to this action.

IN WITNESS WHEREOF, I have subscribed my name on this date: February 4, 2020 .



My commission expires:

August 20, 2023

EXHIBIT 36

Food and Drug Administration
OFFICE OF CRIMINAL INVESTIGATIONS
MEMORANDUM OF INTERVIEW

CASE NUMBER:	2016-MWM-709-0576
CASE TITLE:	THERANOS, INC.
DOCUMENT NUMBER:	258754
PERSON INTERVIEWED:	Sarah Bennett, CMS/Division of Laboratory Services
PLACE OF INTERVIEW:	CMS, 7500 Security Blvd., Woodlawn, MD
DATE OF INTERVIEW:	09/12/2017
TIME OF INTERVIEW:	1000 EST
INTERVIEWED BY:	SA George Scavdis
OTHER PERSONS PRESENT:	See below

On September 12, 2017, the case agent interviewed Sarah Bennett, Centers for Medicare and Medicaid Services (CMS), regarding a CLIA (Clinical Laboratory Improvement Amendments) survey she conducted of Theranos, Inc.'s (Theranos) high complexity laboratory in 2015. Bennett is a medical technologist in CMS's Division of Laboratory Services (DLS). Also present during the interview were the following: AUSA Jeffrey Schenk, United States Attorney's Office for the Northern District of California; Jessica Chan, Securities and Exchange Commission (SEC), Division of Enforcement (DOE); Rahul Kolhatkar, SEC, DOE; Monique Winkler, SEC, DOE; Gary Williams, HHS, Office of the General Counsel (OGC); and Kelsey Schaefer, FDA, Office of the Chief Counsel (telephonically).

Bennett has a Bachelor's of Science degree in medical technology, and she has worked in laboratories for over 28 years. In 2007, she went to work for the Maryland state agency that conducted CLIA surveys, and she was the supervisor of the Laboratory Licensing and Surveying Department. That department was responsible for the implementation of CLIA. In addition to being a supervisor, she conducted surveys.

Bennett explained that a CMS Form 2567 is called a Statement of Deficiencies and Plan of Correction. Bennett was responsible for drafting a portion of the one issued to Theranos, and Gary Yamamoto was responsible for drafting the other portion. Bennett said that she can speak to the parts of the Form 2567 that she wrote, and that she wouldn't have written a deficiency if she didn't have the expertise to write it. In order to be able to write a deficiency, one needs to know the CLIA regulations, the requirements that are applicable to the laboratory being surveyed, and whether what is observed during a survey rises to the level of a deficiency. Bennett works with the Form 2567 within the course of her employment at CMS.

Bennett explained that with regard to CLIA, some states have their own regulations, and a laboratory that is housed in that state must follow whichever set of regulations is more stringent — either the state's, or the CLIA regulations. She further explained that only some of the state regulations may be more stringent than the corresponding CLIA regulations; it's not all or nothing. The State of California has its own state regulations, but Bennett is unsure whether those regulations are considered more stringent than the CLIA ones. Normally, if a state agency is conducting a laboratory survey, it would be looking at both the federal and the state regulations that apply to a laboratory. When Bennett surveyed Theranos, she was only looking at the laboratory's compliance with the federal CLIA regulations, because she was conducting a federal survey. When Bennett was a surveyor for the State of Maryland, she looked at deficiencies under both the state and federal CLIA regulatory schemes, and she would generate two different Form 2567s to reflect that. It's up to

the individual states as to whether they want to combine the results of a survey on one form or do them separately. Theranos never stated to CMS during or after the survey that they were following California state regulations as opposed to CLIA regulations.

In order to become a CLIA certified laboratory, a laboratory first completes and submits a CMS Form 116 (CLIA Application for Certification). When the Form 116 gets filed and approved, the system generates a CLIA number. Within 3 to 12 months after the generation of the CLIA number, the state conducts a survey of the laboratory, which results in either a finding of compliance or in a finding of deficiency. CMS collects a laboratory's Form 116 each time it conducts a survey. If a laboratory makes certain changes, like replacing its laboratory director, then it must complete and submit a new Form 116. CMS typically doesn't get that first Form 116 generated by a laboratory, because the initial survey is conducted by the state. The first two surveys of Theranos were done by the State of California, and CMS did the third. The first state survey occurred in either 2011 or 2012, and the second one occurred in 2013. It would have been normal for the state to survey them in 2015, however, due to the media attention Theranos was receiving at the time and due to the complaints CMS had received about Theranos, it was determined that Bennett and the CMS regional office (Yamamoto) would conduct the survey instead.

In 2014, Theranos came to CMS to explain their device and their business model. Bennett said that it's unusual for a company to do that. She believes that Elizabeth Holmes (Theranos's CEO) wanted to convince CMS that Theranos didn't need a CLIA certificate for their business model. Theranos gave them a flow chart of a business model which showed that the Theranos black boxes would be at sites in Walgreens, that they would be used to collect blood, and that they would send a signal back to Theranos's headquarters in Palo Alto, CA. CMS told them in that meeting that Theranos had to go to the FDA with their device. CMS also told Theranos at that meeting that Theranos did indeed need a CLIA certificate. Penny Keller and Judy Yost from CMS were involved in that meeting. Yost has since retired. Bennett has some e-mails relating to that meeting that she promised to provide at a later date through OGC.

CMS is responsible for the implementation of the CLIA regulations, which are designed to ensure the accuracy and reliability of laboratory testing. FDA interacts with the manufacturers of devices and test systems. CLIA interacts with the laboratory to make sure the laboratory is using those devices and test systems in the manner in which they are supposed to be used. In other words, the manufacturing of tests is FDA, and the running of laboratory tests is CLIA. A laboratory can run either FDA approved tests or tests that are unapproved which are called laboratory developed tests (LDTs). If a laboratory tweaks an FDA approved test, then there are other requirements under CLIA with regard to additional testing that the laboratory must perform to validate that test.

During the 2015 survey, Theranos didn't talk with Bennett about significant modifications that it was making to FDA cleared or approved tests that it was using in its CLIA laboratory. While there, Bennett looked at the Edison device, which Theranos had discontinued using by the time of the survey. Most of her review was "paper" review; she focused her review on their validation studies, which had to include accuracy, precision, reportable range, reference range, analytic specificity, and analytic sensitivity. She focused on quality control (QC) as well as on quality assessment (QA) issues that Theranos had identified in their QA monitoring program. Bennet explained that QA monitoring involves investigating problems with equipment, finding and implementing corrections, and monitoring those corrections. Yamamoto focused on Theranos's pre-analytic data.

Bennett does not use a CLIA "checklist" when she conducts laboratory surveys. While conducting a survey, the areas Bennett focuses on are QC, QA, and proficiency testing. She picks those areas because those are areas where she can usually discover if there's a problem. Problems in those areas show there is some kind of breakdown in a company's overall quality system, because it demonstrates that the laboratory can't identify issues that arise. Bennett also looks at personnel qualifications very closely while she's on a survey.

The 2015 Theranos survey was both a recertification survey and a complaint survey; it's not unusual for CMS to combine surveys in this manner. The complaints regarding Theranos were received by Yamamoto in CMS's Region Nine. Bennett has copies of the complaints that she will gather together and give to OGC.

Bennett said that Yamamoto received a complaint from a former Theranos employee. Additionally, the State of New York received a complaint, which they said they sent to CMS; however, CMS said they never received that complaint, so nobody within CMS could track that down. CMS started its on-site survey of Theranos in September 2015, and it came back to finish the survey in November 2015. The survey was announced to Theranos ahead of time. During the survey, CMS found that Theranos had a lot of procedures that had been signed by their new laboratory director just a day or two before the start of the September survey.

CMS conducts biannual CLIA surveys of a laboratory; so, in 2015, Theranos was due to be surveyed. If a laboratory submits a new Form 116 because it has hired a new laboratory director or for some other reason, that fact would not trigger a CLIA survey. Typically, a recertification survey is conducted approximately six months before the expiration of a laboratory's CLIA certificate. If there's some extenuating circumstance, like with Hurricane Irma or Hurricane Harvey, surveys of affected laboratories won't be completed within the two-year time frame. If the state agency tries to schedule a survey and the laboratory gives them the run around, normally the state agency will notify the CMS regional office. The CMS regional office can take enforcement action, whereas the state cannot. They can continue to try and reschedule, and if the laboratory continues to refuse, CMS can cite them for refusing an inspection, which allows CMS to take certain enforcement actions. Bennett doesn't know if any of this happened with Theranos. The state agencies are agents of CMS; they are not CMS employees.

Bennett explained that it is unusual that CMS sent central office personnel (Bennett) out on the Theranos survey. With that being said, Bennett had experience as a surveyor and she was asked to go by her supervisor, Karen Dyer, the director of DLS. Bennett said that DLS is also known as the CLIA program. Bennett has conducted CLIA surveys for CMS on two other occasions. Normally, re-certification surveys are conducted by the state agency, but because of the media attention associated with Theranos, the decision was made to send Yamamoto and Bennett. John Carreyoru (a reporter for the Wall Street Journal) had been in contact with CMS about an article he was writing on Theranos. Carreyoru talked to Dyer about the article. He has never spoken with Bennett. The CMS regional office conducts federal jurisdictional surveys. For instance, the National Institute of Health would be surveyed by CMS's Philadelphia Regional Office. Also, federal surveyors would be responsible for surveying the Maryland state laboratory, for example. Bennett was a natural to ask to do the survey because she has survey experience, and she had done it twice before. Most of the people within DLS are not surveyors. CMS knew the day that FDA went in to inspect Theranos (in August 2015). Bennett thinks FDA notified Dyer, and that Dyer told Bennett. The FDA inspection played no role in CMS deciding to involve its central office in the Theranos survey. Surveys are not coordinated between FDA and CMS; the two agencies have different authorities and they look at different things. They have different regulations, standards, and requirements that they're looking at. For instance, FDA would have been looking at the manufacturing, and CMS would have been looking at the testing. Typically, a laboratory is not both a manufacturer and a laboratory conducting tests.

Bennett said that going on site at Theranos was "very interesting." Everything there is kept behind locked doors. She'd never been on a survey before where there was so much security, which she described as men wearing black suits and ear buds. There was never a time when Bennett and Yamamoto were not in view of a security guard; they even had to be escorted to the bathroom. Bennett's been on dozens of surveys and has never seen that before. Theranos had both in-house attorneys and outside counsel at the survey, which is not something you'd typically see. It's also not typical to have stickers put on everything saying that it's exempt from release under FOIA. Bennett noted that it was unusual to ask a company for a document, for it to take the company a long time to produce it, and then for the document to be non-responsive; that is what happened with Theranos. CMS told them when they came back in November that practice was not acceptable, and that CMS would assume that if Theranos couldn't produce a document when CMS asked for it, then Theranos didn't have it.

Bennett didn't talk to any previous Theranos surveyors prior to the 2015 Theranos survey. She expected there to be some security because of the mystery surrounding the Edison device, which was proprietary, but she didn't expect that level of security in the non-proprietary laboratory. She had never surveyed a laboratory that developed a device before. The non-proprietary side of the Theranos laboratory was the portion of the laboratory where Theranos was using traditional FDA approved devices. Bennett didn't

inspect the portion of the laboratory that tested blood obtained from finger stick testing; she only inspected the portion where Theranos was using samples obtained from venous blood draws. During the survey, Bennett and Yamamoto went into one laboratory that was portioned off, with Theranos telling them that the side portioned off was their research and development (R&D) area, and that they were not permitted to go in there. It's typical for a company to tell CMS that they can't go into an R&D area.

Bennett explained that when CMS initiates a complaint survey, the survey is typically focused on the subject of the complaint; however, if during that survey other issues are found that are not related to the complaint, then the scope of the survey can be expanded. Since the Theranos survey was both a recertification survey and a complaint survey, there wasn't a separate "portion" of the survey done to address the complaint; they just incorporated what the complaint issues were into the recertification survey. In the case of the Theranos survey, the complaint that CMS received was about proficiency testing. More specifically, the complaint alleged that they were testing patients on their proprietary device, but doing their proficiency testing on the FDA approved devices. Proficiency testing is a CLIA requirement, and there are regulated analytes and unregulated analytes. Proficiency testing normally consists of three events a year with five samples being tested for regulated analytes. The proficiency testing provider sends the blind samples to the laboratory, the laboratory runs the samples and sends the results back to the provider, who then grades the laboratory. The proficiency testing provider sends schedules to the laboratory, so the laboratory knows when the blind samples are coming. During the survey, CMS could not find any evidence to substantiate that part of the complaint about Theranos's proficiency testing. Bennett noted that it would have been very difficult to substantiate that, because Theranos could have hidden that easily and there would have been no way for CMS to find that unless CMS was given specific information about where to find it. The other part of the complaint that CMS received was that the QC on the Edison devices was not acceptable and Theranos was still reporting patient results. That part of the complaint was substantiated during the survey.

CMS requires that a laboratory run two levels of QC for each day of patient testing, and that the laboratory follow the manufacturer's ranges for those tests. A laboratory must verify those ranges before doing a new lot of QC. If a laboratory has its own device, it has to come up with its own QC procedures. Theranos was not following its own QC procedures, and they were still reporting patient results. Bennett explained that there are assayed controls and there are unassayed controls, where a laboratory has to determine what ranges are acceptable. Theranos was using commercial controls, which means they were purchasing control material to use on the Edison. On any system, a laboratory has to do QC. Most control material is purchased commercially; it's not developed by the laboratory or the device manufacturer. So, when Theranos tests the control material that they're using to do QC, they have to be within the ranges of what the manufacturer sets for that control. Theranos can't change those ranges. The package insert will list the devices that are cleared to be used with that control material, and it will give acceptable range limits for those devices. For the Edison, that device would not have been on any package insert for commercial control materials, so Theranos would have had to come up with their own way to determine QC values. With regard to QC testing, CMS is looking to see that Theranos is following its QC ranges. CMS is not assessing the validity of the ranges they've come up with, they're just looking to see if Theranos is following them. CMS is also checking to make sure that Theranos is not conducting patient tests when its device is out of range.

Bennett found many instances where Theranos ignored their own procedures for acceptability of controls. CMS would comment on it if they weren't following their own procedures, or if they were using assayed controls and they weren't following those ranges. CMS looked to see if Theranos developed their own ranges and whether their QC testing results were within their own definition of what was acceptable. During the survey of Theranos, Bennett asked for QC records for a particular date range in order to check this. She explained that what she normally gets back from a laboratory in response to this request is something called a Levy-Jennings Graph. This is generated by a computer, and it is used for QC only. She explained that the graph has a range of controls and a line that represents the mean. If a laboratory gets a value that is outside the range of controls, they have to react to that. For Theranos, those graphs were created by a computer (an LIS, or laboratory information system) that takes the controls and puts in the testing values. Theranos was using Westguard as a basis, but they were cherry picking what part of Westguard they wanted to use.

CMS looks at a laboratory's procedures and it looks to see that they are running them when they say they

are supposed to be running them. CMS doesn't look to the patient data. If the QC is problematic, there is no way to assess whether the patient data is accurate and reliable. If the laboratory runs the controls in the morning and they are unacceptable, then they should not be running patients after that. The standard deviation is used for controls, not for patients; patients have a normal reference range. Patients are either going to be abnormally low or abnormally high. There is also a reportable range. CMS doesn't require that a laboratory track patient test results, but they do require a laboratory to address patients who were tested during a period when the laboratory was not functioning as it should have been.

Bennett will look at patient testing when she's on a survey if there's a problem with proficiency testing or QC. She wants to see if the laboratory has identified whether there was a QC problem, and if they continued to report patient results when there was one. There's no value to the raw data if you're not using it in context with something else. One place you might look at patient results is when you're looking at the final report with regard to what the LIS said, but Bennett didn't look at that on the Theranos survey. QC results have to be reviewed by an appropriate person at the laboratory. When Bennett asked for Levy-Jennings reports from Theranos, they went to their computer, put the dates in, and printed them out for her. Her understanding was that the information went right from their device into the LIS; it was not manually entered. The LIS system is populated with patient and QC data. The one device that Bennett saw at Theranos fed its results directly into the LIS.

Surveyors are the ones that decide what deficiencies to cite. Before CMS concludes the survey, they tell the laboratory what deficiencies they've found. With Theranos, Bennett sat with them at the end of every single day and told them what she and Yamamoto found. Sunny Balwani was there every day. Holmes was not present during the September survey, but she came in November and followed Bennett around for two days. Bennett thinks CMS was at Theranos for three days in September and for four days in November. In November, Balwani went with Yamamoto, and Holmes went with Bennett. Theranos wanted details every day on what CMS had found, and at the end of the survey, CMS went over everything again with them. Bennett has a computer program that she writes the deficiencies in, and the program creates the Form 2567. The "Findings" section is the specific evidence that supports the "Deficiency" that is cited. Bennett has her handwritten notes from the survey, and she said that not everything in her notes is transferred into the Form 2567. Karen Fuller, Yamamoto's supervisor, was at the survey to observe, but she didn't take notes. During the survey, CMS received documents from Theranos that they took with them. Holmes was not happy and expressed her displeasure at the end of each day in November at what CMS had found. Heather King was very assertive in trying to convince CMS that what they were seeing wasn't really an issue. Bennett's survey notes are geared toward what CMS was looking at with regard to CLIA compliance. If someone from Theranos made a comment that was a confirmation of something CMS saw that was a deficiency, then Bennett would have put that in the notes.

CMS started to create the Form 2567 after the September part of the survey, and it was completed after the November portion. CMS normally creates that form at the end of the survey. Bennett was looking at proficiency testing first and she found issues there, so she would have known on the first day of the survey that she would be issuing a Form 2567.

Bennet explained that within each condition there are multiple standards. If there is non-compliance, the surveyor has to make a determination if it is just a "standard level" deficiency or if it rises to a "condition level" deficiency. If a laboratory sends a patient test report out and later finds out that it is wrong, the laboratory is required to do a certain report and send it to certain people in response. Within each of these component areas you have to react to it, fix it, and monitor it. Title 42 CFR 493 lays out all of the CLIA regulations.

CMS knew when they left in September that Theranos was likely to get "condition level" deficiencies, and that they were IJ (In Jeopardy). IJ is a "condition level" deficiency that has the potential to cause patient harm. CMS hadn't made a final determination at the time of the survey. It's not unusual for CMS to make a determination of IJ. They talked about it with Theranos, but hadn't made a final decision. They were waiting for Theranos to produce a document related to PT/INR. PT/INR stands for Prothrombin International Normalized Ratio, which is a test to see if Coumadin is working. This test is measured in seconds. Bennett had discovered several issues with Theranos's INR, and one was that they had entered a mean normal

prothrombin time. She explained that a laboratory has to run something like 20 samples and come up with an average. In order to calculate the INR, you need that number. Theranos had a number in the computer and a document that showed that their INR had been calculated three days before CMS got there. Despite calculating that number three days prior to the survey, the reagents had been in use for six months prior to that, and Theranos couldn't produce a document showing that the INR had been arrived at for testing during that period. Doctors need to know that INR number because it speaks to how prone a patient is to getting clots or to bleeding out. CMS discovered this issue in September, and they went over this with Balwani and King at the end of the day. Bennett remembers that the conversation took place at the Theranos instrument. Bennett said she needed that document and they couldn't produce it. Another issue that CMS found was that QC test results on their device had been out of range multiple times, and yet Theranos was still reporting patient results during that time. Theranos's solution was to simply adjust the mean. Langley G., who was the Theranos laboratory director at the time, was the individual who was said to implement that solution. Another issue that CMS found had to do with sample stability. Theranos missed that the manufacturer of the Thromboplastin that they were using changed the stability on their package insert. The package insert changed the stability from ten days to two days, and for six months Theranos was using that product with a five-day stability protocol. At the time of the survey, Sunil Dhawan was the Theranos lab director, and Bennett saw him once for a total of 30 minutes, and he talked to no one. During a survey, the laboratory director is not required to be present.

The PT/INR was one of the reasons that CMS called IJ. They couldn't tell if that six-month period whether the patient testing was done correctly. Theranos wasn't even calculating their own reported values correctly. The other part of Theranos that Bennett looked at during the survey that was problematic was all of the validation and QC data for the Edison device. Theranos continued to report patient values despite having these QC problems. Bennett noted that Theranos had stopped using the Edison device by the time of this survey. Regardless, CMS can still look at any records from the previous two years of the date of inspection. CMS also cited Theranos for having a procedure that was not signed by the laboratory director. Before a laboratory director signs off on a procedure, it's not really usable in the laboratory. CMS sees this often. They also see unqualified personnel as a common issue in laboratories.

One deficiency can lead to a determination of IJ, or it can be a mix of things. If CMS makes an initial determination of IJ, the company must work relatively quickly in order to abate that. In this case with regard to the timelines for enforcement, Theranos was given much longer than any other laboratory would have been given. In Bennett's opinion, this was due to the number of high profile people that were involved. The letter CMS sent to Theranos on January 25, 2016, is the IJ notification. Normally, CMS doesn't put exactly why something is IJ in its notification, other than that the determination is IJ. The allegation of compliance that a company sends in response must show that they've corrected the deficiency at the time of the submission. In Theranos's case, the evidence did not support a credible allegation of compliance. The letter that CMS sent Theranos in March tells them exactly why their response was not credible.

CMS cited Theranos for five "condition level" deficiencies. CMS was able to remove the testing personnel "condition level" deficiency, because Theranos removed the person in question from his position. At the time that CMS sent its July 2016 letter to Theranos, four "condition level" deficiencies remained. The main reason CMS called IJ was because of all the issues they found in hematology, not just the PT/INR issue.

The letter CMS sent to Theranos in July 2016 was the "Impose Notice," which told Theranos that the proposed sanctions would be imposed as of the date of the letter unless Theranos appealed. Theranos approached CMS about a settlement. Because CMS called IJ, they could limit Theranos's CLIA certificate by saying they couldn't test hematology after a certain time without waiting for a decision from an administrative law judge (ALJ). In Theranos's written responses to CMS in which they attempted to show they had corrected the cited deficiencies, Theranos would send CMS a copy of a faxed sheet saying something was corrected along with a corrected report, but CMS could never marry the two together; so, CMS never knew if Theranos actually notified all of their affected patients. Bennett said that over 50,000 patient test results were implicated. To date, CMS doesn't know if all of the affected patients have been notified. Theranos made the decision to void the test results; CMS didn't tell them to do that. CMS tells the laboratory they must fix a deficiency and the laboratory decides how they're going to fix it. Theranos came to CMS

sometime after the IJ determination to tell CMS how hard they worked and how they were in compliance, all in an effort to keep their CLIA license.

In this case, Theranos appealed after they received the July Impose Notice. Bennett explained that after CMS sends an Impose Notice, CMS can't talk to the company until the company appeals. This appeal goes to the Civil Remedies Division. Theranos both appealed and approached CMS about a settlement. When the laboratory files an appeal, it gets assigned to an ALJ, and the ALJ tells the company that they have to send in all of the documents that they're going to be using prior to the date of the hearing. CMS doesn't create any new documents on their side, but Bennett doesn't know if Theranos created new documents to submit as their evidence. In this case, there was no decision by the ALJ because a settlement was reached resulting in Theranos withdrawing their appeal. Bennett was not involved in the settlement at all. She assumes it was Kate Goodrich and maybe David Wright, but she has no idea who was involved in the settlement. Bennett suggested that the case agent ask Dyer to find out who was involved. Bennett said that anytime CMS revokes a laboratory's CLIA certificate, the owner/operator and the laboratory director are barred from running a laboratory for 2 years.

Bennett explained that it's CMS's ten regional offices that propose and impose sanctions. In this case, the letters sent from CMS to Theranos came from the regional office. All of the letters that went to Theranos after the first January 2016 letter went all the way up through CMS to at least Goodrich's level. This is not the normal process; it's usually handled by the region.

If CMS calls IJ, it gives CMS the ability to limit or suspend the CLIA certificate prior to a decision of the ALJ. That occurred in this case. CMS limited Theranos's CLIA certificate three days after Theranos received the letter. The "barring" of the laboratory director and the owner/operator from running a laboratory for two years occurs only when the revocation is imposed and final. There are only certain things a laboratory can appeal, and those things are called "initial determinations." In this case, revocation was never imposed. Bennett doesn't know the terms of the settlement other than hearing that Theranos's Arizona and California laboratories were all in one settlement, that Theranos voluntarily ceased testing at both laboratories, and that the laboratory directors wouldn't run another lab for a certain period of time. She heard that revocation was not a part of the settlement. The survey of the Arizona laboratory was in August or September of 2016, and Bennett and Yamamoto did that survey as well. When they were in the Arizona laboratory, they discovered significant issues and a Form 2567 was issued. The survey of the Arizona laboratory led to a determination of IJ as well for some of the same issues that CMS saw at the California laboratory. Theranos's Allegation of Compliance essentially said, "We were planning on closing before you came in, and we're closing." The laboratory director, Daniel Young, was present during the entirety of the survey. He was especially difficult to deal with, and talked in circles. He was there for the California laboratory survey as well, and spent most of his time with Yamamoto.

A revocation means that the CLIA number can no longer produce laboratory results. The difference between a revocation and a settlement is there's no black mark on the laboratory's record in the case of a settlement--they don't have a revocation on their CLIA history.

There's no separate form surveyors create to memorialize interviews they've conducted during a survey. They just have the information in their notes.

Bennett explained that CMS hadn't looked at the Edison device at the start of the Theranos survey in September and hadn't addressed all of the issues in the complaint, so that's why they had to go back in November. She said that, as far as she's concerned, if you don't have the right INR result there is a potential for patient harm based on that because you can't have any confidence in the patient results. She looked at patient data and saw three or more different lot numbers of Thrombin, and she couldn't even tell where the patient result came from when she looked at the data. It's the laboratory's responsibility to look at that and decide if any patients have been affected; it's not CMS's job.

The CLIA regulations have nothing to do with payment and billing. All Bennett can tell someone is whether a laboratory has met the CLIA regulations. She said there is a provision in their CLIA regulations with regard to

criminal violations, but it's not for CMS to determine whether something constitutes a criminal violation. During the interview, Bennett cited the provision as being section 493.1806(E)

In January 2014, Theranos came to CMS to have a meeting, and Holmes attended. Bennett doesn't know if there were any minutes taken and kept for that meeting, but she took a few notes. During the meeting, Theranos gave CMS some documents, including a flow chart. Dyer, Penny Keller, and Bennett were there. She doesn't know if Balwani attended. Theranos requested the meeting in order to show CMS their new technology, and because they thought they didn't need a CLIA waiver to put their black boxes in Walgreens. CMS told them they needed to go to FDA to get the CLIA waiver. Theranos didn't bring their Edison device to the meeting, and Bennett doesn't recall who from Theranos presented. They talked more about their business model—that they had a proprietary device to do a finger stick that would go into the Edison device, and that the Edison device would send an electronic signal to Palo Alto, CA, where the results would be interpreted. CMS considers a test system from the beginning to the end. In CMS's view, the device was receiving a specimen and doing the testing and that's where the results were generated, even though they were in electronic form. Theranos made some statements about what their hopes were with regard to tests they would run on the Edison. Bennett didn't have the impression that they were using the Edison at that time. The meeting was probably an hour long. They told Theranos if they wanted to get their device approved they had to go to FDA. They also told Theranos that if they wanted their device waived they had to go to FDA. Bennett was not involved with any CMS follow-up to that meeting.

There are three levels of testing: "waived," "moderate," and "high" level complexity. If a laboratory is only performing waived testing, they only need a certificate of waiver. Waived tests are tests where, in most cases, an inaccurate result won't cause patient harm (i.e. a urine pregnancy test or a blood glucose test). Any time you have a waived test and don't follow the manufacturer's instructions, it becomes a high complexity test. With moderate complexity testing, the personnel requirements are not as stringent as they are for high complexity. Performance specifications are the same for both moderate and high complexity. According to Bennett, performance specifications is CLIA speak for validation. FDA is responsible for the classifications of waived, moderate, or high. The finger stick samples Theranos was diluting and putting on traditional devices were high complexity because they had modified the manufacturers' instructions. The Edison device was high complexity because it was considered a laboratory developed test. All of the tests run on the Edison device were high complexity. A lab developed test is never CLIA waived.

Bennett said her understanding was that the state surveyor who performed the 2013 Theranos survey was unaware that Theranos was using the Edison device at the time and that the surveyor only inspected the traditional side of their laboratory.

Bennett said that pre-diluting samples on a regular basis is unusual, but that there is nothing in the CLIA regulations that prohibits Theranos from doing that. If they are diluting samples, they have to perform the validation.

At some point, Bennett was told by her management to stop communicating with Theranos, be it over e-mail or telephonically.

SUBMITTED: Electronically submitted by GEORGE SCAVDIS

GEORGE SCAVDIS, SPECIAL AGENT DATE: 10/02/2017

APPROVED: Electronically approved by MARK MCCORMACK

MARK MCCORMACK, SPECIAL AGENT IN CHARGE DATE: 10/03/2017

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cc: Prosecution

ATTACHMENTS: None

EXHIBIT 37

Food and Drug Administration
OFFICE OF CRIMINAL INVESTIGATIONS
MEMORANDUM OF INTERVIEW

CASE NUMBER:	2016-MWM-709-0576
CASE TITLE:	THERANOS, INC.
DOCUMENT NUMBER:	261269
PERSON INTERVIEWED:	Gary Yamamoto, CMS
PLACE OF INTERVIEW:	USAO, San Francisco, CA
DATE OF INTERVIEW:	12/12/2017
TIME OF INTERVIEW:	0900 PST
INTERVIEWED BY:	SA George Scavdis
OTHER PERSONS PRESENT:	See below.

On 12/12/2017, the case agent interviewed Gary Yamamoto, State Oversight and CLIA Branch, Division of Survey and Certification, Centers for Medicare & Medicaid Services (CMS), regarding a survey he conducted of Theranos, Inc. in 2015. Also present during the interview were the following: AUSA Jeffrey Schenk, United States Attorney's Office for the Northern District of California (USAO/NDC); AUSA John Bostic, USAO/NDC; Cameron Purves, Federal Bureau of Investigation; Christopher McCollow, U.S. Postal Inspection Service; Mark Katz, Securities and Exchange Commission; and Melissa Manson, Health and Human Services, Office of the General Counsel.

Yamamoto participated in a survey of Theranos's California laboratory in 2015, and he worked with Sarah Bennett (Survey and Certification Group, Center for Clinical Standards and Quality, CMS) on a survey of Theranos's California and Arizona laboratories in 2016.

Yamamoto first met Elizabeth Holmes and Sunny Balwani in 2012. FDA relayed a complaint to CMS that FDA had received from the Department of Defense (DoD), and CMS's Central Office asked Yamamoto's office (the San Francisco District Office) to look into the matter. The complaint that was relayed was that Theranos was developing a test system, and there were questions as to whether that system would need a CLIA certification. The complaint had less to do with the technical aspects of the test system, and more to do with whether the Theranos business model would have complied with the CLIA regulations in terms of CLIA certification. Yamamoto called Theranos and spoke to Balwani. The two scheduled a meeting at Theranos for Yamamoto to ask more questions about the issues relayed to CMS by FDA. The meeting in 2012 was attended by Yamamoto, Balwani, Holmes, and other people from Theranos.

Yamamoto explained that the CLIA regulations are about insuring that there is a minimum level of quality for testing that is performed in the U.S. That status of FDA approval for a given test system is what determines which parts of the CLIA regulations apply. FDA is concerned about the actual test system, whereas CMS is more concerned about where the system is used and how it is used in terms of quality. It matters to CMS where a test system is located, where the test is being performed, and how the system is being used. Apparently, what Theranos wanted to do was set up proprietary devices in locations with the idea that there be only one CLIA certificate at Theranos that covered all the locations. Wherever the proprietary instrument was located was where the specimen would be introduced into that system, and then there would be an electronic transfer of data from that test system to some other location. In Theranos's mind, the place where the electronic data was transferred to was the location where the test was being performed, and that

was where they believed the CLIA certificate needed to be. Yamamoto explained that's not how the test system works. He explained that the reaction doesn't take place where the electronic data is transferred to; it takes place where the instrument meets the specimen, and that's how CMS views it. Therefore, Theranos would need a CLIA certificate at the location of the instrument as well as at Palo Alto, CA, where the data was electronically transferred to. AUSA Schenk asked Yamamoto how CLIA certification would apply to a device such as a glucose meter. Yamamoto explained that if an individual patient uses an instrument on themselves at their home, then that does not require a CLIA certificate. But, if a health provider was coming into a home to provide care with that same instrument, that person would require a CLIA certificate.

Yamamoto said the Theranos business model was "novel." The complaint from DoD was that Theranos was exploring this business model of placing its proprietary devices in combat zones and transmitting information into a central location. After Yamamoto received the complaint through CMS's Central Office, he called the number on the CLIA certificate in Palo Alto and he was eventually connected to Balwani.

The Theranos location at Palo Alto had a laboratory that had been previously CLIA certified. If a laboratory wants a CLIA certification, the first thing it does is apply for one. The state of California has its own laws governing the certification of laboratories. They issue a state license to a laboratory after they conduct a survey of the laboratory. Once they issue a state license, (CLIA contracts with the states) the CLIA application gets processed. Once the laboratory has paid the CLIA application fee, the laboratory enters a "registration period." While they are in that registration period, they can legally perform laboratory tests. Sometime within a two-year registration period, the state agency will survey the laboratory. Laboratories are then certified every two years after that date, which is the laboratory's CLIA certification date. Yamamoto explained that the state waits to do an initial certification survey until after a laboratory is performing tests because the state wants to see some actual patient test results in order to assess how that entity would operate. When Yamamoto went to Palo Alto, Theranos had already had their initial certification of their laboratory. California conducts on-site visits for their own licensure requirements. In addition, all their CLIA certification surveys are conducted on-site as well. Melba Herrera was the California state surveyor that conducted the Theranos initial certification survey.

Yamamoto asked Theranos why they had a laboratory in Palo Alto. Their explanation was that they wanted to have a laboratory to understand the real world implications of how a laboratory worked, so they could figure out how what they were developing fit into a laboratory. They weren't using their proprietary equipment in their laboratory. Their laboratory was acting as a reference laboratory for physicians in the area. Yamamoto doesn't know what Herrera learned in her survey of Theranos. While he was in Palo Alto, he didn't see them using their proprietary system; they told him they were still developing it. There was nothing that would come under the jurisdiction of CMS at that time regarding their proprietary equipment, because Theranos said it was something they were developing.

Yamamoto recalls Balwani and Holmes being at this meeting in 2012, and he thinks the meeting occurred in June or July. He told Balwani they received an inquiry about what Theranos was doing. His initial conversation with Balwani was over the telephone. Yamamoto told him that if the Theranos device was distributed in certain locations, then each one of those locations required its own CLIA certificate. Balwani said the Theranos device was in development and that they weren't currently using it. Yamamoto said that CMS's Central Office asked him to go to Palo Alto. When Balwani was returning Yamamoto's call, he identified himself as either the CEO, the COO or the President of Theranos.

Yamamoto went to Palo Alto approximately two or three weeks after his telephone call with Balwani. He can't recall who else from Theranos was at the meeting beside Balwani and Holmes. The Theranos business model was unusual, and CMS had not seen that before. CMS was curious as to the scope of the testing Theranos was conducting. These reasons explain why CMS felt the need to do a site visit. During the meeting, Theranos talked a lot about their working relationship with FDA. Yamamoto told them to continue to work with FDA, but cautioned that if it moved over to "real life" then they may have CLIA certification issues. His sense was Theranos didn't know who CMS was and how they played into things, and that they were more comfortable working with FDA. Theranos's focus during the meeting was on asking questions that he couldn't answer. They seemed confused as to where the line was drawn between FDA and CMS. In

general, the scope of their questions were procedural questions about FDA processes. Yamamoto described the meeting as cordial.

At the time that Yamamoto went to Palo Alto, Theranos had a CLIA certificate at that location, under which they could have performed any type of testing. The issue was that Theranos believed that CLIA certification covered any outside locations that utilized their proprietary device. Yamamoto explained to them that they would need a CLIA certificate for each of those locations. Theranos didn't react to that, they just listened. Yamamoto asked them when the launch date for their device was. They were very elusive and didn't want to tell him.

The CLIA regulations accommodate both FDA approved and non-FDA approved test systems; different requirements apply to each. A laboratory can use LDTs (laboratory developed tests) under their CLIA certification, provided they meet the CLIA requirements and provided their documentation establishes that they've set certain test parameters prior to reporting patient test results. As an LDT, the laboratory must establish sensitivity, specification, limitations of their test system, etc. Assuming the company had all of that, they wouldn't have needed a different or additional CLIA certificate.

The CLIA requirements for LDTs are analyte dependent, but the general requirements are all the same. There are requirements to notify CMS if a laboratory makes changes to its test menu. CMS provides CLIA certification and also designates specialties and sub-specialties for a laboratory. If the laboratory chooses to perform a test outside of its specialty, they would have to notify CMS and the state agency would determine whether there needed to be another survey to see if the laboratory could add those additional specialties or sub-specialties.

If Theranos is using an off the shelf instrument that is FDA approved, the CLIA requirements are different than if they're using their proprietary test. Potassium is not a different sub specialty of calcium (both are routine chemistry), so if they added one of those tests, there would be no need to add a sub specialty to their CLIA certificate. Sometimes tests are characterized by methodology, and sometimes they are characterized by the analytes themselves. There is a requirement to notify CMS within 30 days of a change in a laboratory's testing menu. If that failure to notify is combined with other transgressions or problems or deficiencies, then it would add to the picture as far as Yamamoto is concerned; but, if it was just the laboratory failing to notify CMS of a change in its testing menu, then it wouldn't result in a revocation of the CLIA certificate. CMS is the one that pulls the CLIA certificate, not the state. CMS contracts with the states to act as their agents, which obligates them to perform certain tasks, but in terms of any action taken against a CLIA certificate, that's always taken by CMS. If Theranos was performing their tests in a Walgreens without a CLIA certificate at that Walgreens, there would be no certificate at that location to take an action against. It's not really a CLIA issue, so CMS refers those cases to HHS's Office of the Inspector General.

California's state agency, the California Department of Public Health, Laboratory Field Services, has a main office in Richmond, CA, and an office in Los Angeles, CA. All their CLIA activity is centralized in Los Angeles. Since Theranos is in Palo Alto, which is close to San Francisco, Yamamoto made the trip to Theranos instead of someone from the state.

Yamamoto explained that LDT is an FDA concept; it's not terminology that exists within the CLIA regulations. CMS considers tests as being either FDA approved tests or being non-approved tests. The requirements to establish test performance standards prior to issuing patient results are different depending on whether a test is FDA approved or not. With an FDA approved test, the laboratory must verify they can get what the manufacturer says they can get against certain benchmarks. With non-FDA approved systems, the laboratory must establish test performance specifications--this is a CLIA requirement. Any clinical laboratory test requires a CLIA certificate.

CLIA does not require that clinical correlations be one of the parameters of a test system. CMS looks at it as laboratory science and whether the test is meeting the bench marks that have been established, and not whether the test result means a specific thing. It's supposed to be the physician that does that. He believes that when FDA approves a system that's one of things that FDA is looking at it. CMS is looking at the

quality of the test result. The physician makes the determination as to what it means. CMS checks the accuracy of the test, because they're seeing if the test system is calibrated, whether QC (quality control) was done, etc. A laboratory can't just pull their reference ranges out of thin air. They must have documentation that supports the reference ranges they establish. There are general reference ranges in the literature, but if a specific laboratory is reporting a different reference range, CMS would look to see if the laboratory has documents supporting that range. The CLIA regulations don't specify how a laboratory sets these requirements. The term validation is not in the CLIA regulations. CMS verifies test performance specifications.

During the 2012 meeting at Palo Alto, Yamamoto asked to see the laboratory. What he saw were just third party machines; there were no Theranos devices. Balwani acted as Yamamoto's tour guide. Theranos said they wanted to have experience in a real life laboratory so they could better understand how their developed system would fit into that. Yamamoto asked to see the laboratory that was previously surveyed and they brought him there. There is no requirement to label a laboratory as a CLIA laboratory or to hang the CLIA certificate on the wall. Compliance is a laboratory's requirement, not CMS's.

Part of the CLIA process is that CMS will pull a sample that encompasses the laboratory's test menu, and then it will look through the laboratory's records to see if there is anything more than that. There is a requirement for proficiency testing. Laboratories need to verify testing results twice a year, and one way to do that is through proficiency testing. Proficiency testing did not come up in the 2012 meeting in Palo Alto. Yamamoto left after the tour and didn't have any more interaction with Theranos until 2015.

In 2015, a complaint was lodged with the State of New York regarding Theranos's proficiency testing. New York said that they forwarded the complaint to CMS, but Yamamoto's office never received the complaint. He's since seen the complaint, but he didn't have it prior to the survey. He was, however, aware of the complaint's existence prior to the survey. In 2015 there were a series of articles written about Theranos in the press, and by then a second certification survey had been performed by the State that was not remarkable in any way. By the time of the 2015 survey that Bennett and Yamamoto conducted, Theranos had already come up for their third certification survey. In addition to the complaint in New York, CMS had received a complaint from a Theranos employee regarding QC on other FDA approved systems Theranos was using in its laboratories and regarding issues with their proprietary system and issues with the competency of Theranos's personnel. Yamamoto believes that the complaint in New York was from a man, and the second complaint from the employee was from a woman. He also believes that the New York complaint was related to proficiency testing, whereas the second complaint by the employee had to do with quality issues at Theranos. It was the combination of this complaint, the articles written in the media, and the requirement that Theranos's laboratory be certified every two years that led CMS to send Yamamoto and Bennett to Theranos to inspect their laboratory in Newark, CA. The survey was both a certification survey and a complaint survey.

Bennett and Yamamoto did the 2015 survey as a team. He had not previously done a joint survey with someone from CMS's Central Office. It was unusual for a person from CMS's Central Office to come out and do a survey with him. A laboratory is required to do QC, meaning that the laboratory needs to run QC materials for every day patient test results are reported, and those quality control levels should have a certain test result. The laboratory must hit those ranges to ensure accuracy of the test system. With Theranos, there were issues of patient test results that were out of control (OOC) yet still being reported; this is something that poor laboratories do all the time. Good laboratories don't do that. Good laboratories make sure their QC is within range, and poor laboratories report results when they fail QC. There were issues with calibration and maintenance as well.

The Theranos Newark laboratory was much bigger than the Palo Alto laboratory. So, based on the prior survey history, CMS scheduled the inspection to last a week. They realized in the middle of the week that it would take longer, and it was at the end of the fiscal year, so they had to wait until the next fiscal year to conclude it. The first week of the survey was in August or September, and the survey resumed and concluded in November. Balwani was present during the first week of the survey, but Holmes wasn't. Theranos also had legal representation there as well. CMS doesn't announce complaint surveys, but they

do announce certification surveys. Theranos considered CMS as being there for a certification survey. The survey was announced only as a certification survey, but CMS was doing both a certification and a complaint survey. In addition to Balwani and various attorneys, the laboratory director and the laboratory staff were present during the survey as well. On the second week in November when the survey resumed, the same people from Theranos were present (Balwani, the attorneys, and the laboratory personnel) and they were joined by Holmes and some hired consultants. Yamamoto said it's not typical for legal representation to be at a survey, but it's happened many times before in his experience.

Prior to working for CMS, Yamamoto worked for the State of California. During that time, he conducted at least 100 surveys a year for a period of 5 years. At CMS, they do less surveys, as their role is more of an enforcement one. In any given year, he conducts 15 to 20 surveys. He generally gets involved in high profile or contentious surveys now, so it's more likely that legal personnel are present at the surveys he conducts. He may conduct two or three surveys a year now, and on one a legal representative will be present.

Heather King, Theranos's in-house general counsel, was an active participant in the CMS 2015 survey. Per Yamamoto, she was "freely able to answer questions." She answered a lot of the administrative questions that were asked at the start of the survey. Theranos had outside counsel at the survey as well, but they were more silent. Theranos never challenged CMS's jurisdiction to conduct the survey. CMS's relationship with the laboratory has never been adversarial. Yamamoto doesn't think Theranos was surprised that there was a complaint lodged against them. Bennett and Yamamoto asked questions related to the complaint in the context of the recertification survey, which helped them disguise what the complaint was about. Yamamoto and Bennett would ask a question and people would scurry out of the room, and sometimes they would get the documents quickly and sometimes they would have to wait. Yamamoto and Bennett got so frustrated from waiting that they asked to be taken to the location of the documents, and Theranos said "No, we'll have people get them." They found out later that there was a room next to the conference room that people were going in and out of. Yamamoto thinks part of it was that they didn't have the documents. Some of the documents were electronic, and that could have been part of the reason as well. If they were altering documents, they were doing a poor job of it. Yamamoto thinks that because the deficiencies cited by CMS were directly related to the documentation produced to them by Theranos. Yamamoto and Bennett split up the work of the survey. The managers of those respective sections that Yamamoto and Bennett were surveying would be the ones answering their questions. Balwani accompanied Yamamoto most of the time, and Holmes accompanied Bennett on week two of the survey in November. Yamamoto isn't sure who was accompanying Bennett during week one of the survey (Balwani was accompanying Yamamoto), but he thinks it could have been King. There was a QA (quality assurance) manager that had to answer both Yamamoto's and Bennett's questions, and that caused some delay in getting documents.

During the survey, Bennett looked at Theranos's personnel and she looked at their proprietary device. Theranos received two types of specimens—venipuncture and finger stick. The venipuncture samples were sent to one section of the laboratory, and the Nanotainer (finger stick) samples were sent to another section. A third part of the laboratory conducted microbiology testing. Yamamoto handled the Nanotainer portion of the survey, and Bennett handled the venipuncture portion. Bennett immediately ran into problems. Yamamoto was able to finish his portion quicker, so he moved into other parts of the survey.

The only time Yamamoto and Bennett saw the proprietary instrument was when Theranos gave them a demonstration during the second week of the survey. In terms of the actual instrument, other than the demonstration, they really didn't see it. CMS wasn't aware that Theranos's proprietary device was at a location other than the Newark laboratory. The business model they saw in 2012 was not the business model they saw in 2015. Apparently, sometime between 2012 and 2015 this issue was vetted with the CMS Central Office where Theranos said "This is our business model and this is what we want to do." Theranos was well aware that if they were going to pursue their business model, then they would need CLIA certification. At that point, they had started to open patient service centers that were only collection centers, and the samples were coming into Newark and Arizona.

Balwani found it "interesting" as to the information Yamamoto was finding during the survey. Yamamoto

understood that Balwani was not a laboratorian by trade, and he thinks Balwani found it interesting to see what Yamamoto was seeing. Balwani was being told by his employees that things were much different than what Yamamoto was finding during the survey. None of the survey was adversarial. At no point did Yamamoto think Theranos was hiding something. Yamamoto thinks Balwani was trusting the structure Theranos had established. Theranos had one QA manager, who was not a technical manager, that was only letting certain information go through on the reports, and that was all Balwani was seeing. Balwani would ask a question and he would get frustrated that the person asked didn't readily have the information available. Yamamoto's sense was that the way Balwani was seeing things was not the way it was being presented to him. Clearly Theranos didn't have a good QC system in place. Yamamoto assumes they didn't have a good QA system either. This wasn't a laboratory that he'd want his samples sent to. Yamamoto thinks they were just as surprised as he was as to what he and Bennett were finding.

When Yamamoto first went to Newark to conduct the survey, there was a log in sheet where all visitors signed in. Generally, the log in sheets are just sheets of paper with lines on it, and Yamamoto noticed someone had logged in the previous week named Gerry Hurst. Hurst used to be a CLIA surveyor. Toward the end of the first week of the survey, Theranos asked Yamamoto if they should seek outside consultation. Yamamoto mentioned that it looked like they had already sought outside consultation and that Yamamoto and Bennett knew who that person was. After that, Theranos never let them sign that log again. In the second week, Balwani said that Hurst was there to help them perform a mock survey because they knew CMS was coming, and that Hurst told them they were a really good laboratory. Balwani said they were contemplating taking some type of action against Hurst. During the first week, Theranos asked Yamamoto and Bennett, "What should we do. How should we correct?" CMS doesn't answer that question of how to correct for laboratories. Toward that end of the second week, Balwani said "Oh, you know why Gerry Hurst was here? We thought we were going to be very good and that you wouldn't find problems. We had hired him to do a mock survey for us." Hurst hasn't been in CLIA surveying for about 10 years. He consults for other facilities. If Hurst said they were a great laboratory, Yamamoto doesn't know what he could have been looking at. Yamamoto thinks Balwani was surprised by Yamamoto's findings.

CMS is not in the business of shutting down laboratories; but if a laboratory's paperwork doesn't document that their test results are accurate, then they don't deserve to operate. Yamamoto goes into these surveys with an open mind because he never knows how these things are going to turn out.

By the end of the survey, it was a good conversational relationship between Theranos and Yamamoto and Bennett. It wasn't an "us" and "them." CMS Form 2567 is called the Statement of Deficiencies, and CMS issued one to Theranos in January 2016. Bennett wrote her parts and Yamamoto wrote his. Yamamoto explained that there are condition level deficiencies, and that conditions are the main umbrella, and under the conditions are the standards that define the condition. CMS found the conditions of Non-compliance and of Immediate Jeopardy. They try not to let there be any surprises to a company at the end of a survey. CMS told Theranos they were considering condition level Non-compliance as the survey was unfolding. When Bennett found a coagulation issue during the first week, they told Theranos they were considering Immediate Jeopardy. It wasn't until the second week that Theranos tried to talk them out of it. They told Theranos they were seriously contemplating condition level Non-compliance and that they were considering Immediate Jeopardy as the survey was going on. Sometime during the end of the second week, Holmes kind of said "Is there any other way to look at this? We think it'd be harmful to us." Yamamoto and Bennett told them that they call it like they see it, and they would call Immediate Jeopardy in any other comparable situation. Holmes pleaded with them to not call it Immediate Jeopardy. They listened politely and tried to move the discussion forward.

Yamamoto doesn't think anyone has ever technically questioned the deficiencies and the evidence supporting those deficiencies in the case of the 2015 survey. Holmes never told Yamamoto that their findings were "news to her." She talked more about how Theranos prides themselves on being the best in the industry, and how they want to be the best in the industry. It's not CMS's job to surprise laboratories; they give them multiple opportunities to respond. During the last day of the survey, Theranos wanted them to go through all the deficiencies once again, which took an additional hour and a half. CMS knew that there would be some time before the end of the survey and the report, and they told Theranos that they would have a

period of time to respond to the report. CMS said that if they are seeking remediation than they should start immediately. They told them this was their opportunity to put their best foot forward. The first submission Theranos made in response was not acceptable. Their excuse was that they didn't put forth a comprehensive submission because they thought the response was going to go out to the media. It appeared to CMS that Theranos wanted to make corrections and do the best they could, but ultimately that's not what happened. Their first submission and subsequent submissions weren't acceptable.

It wasn't until after the deficiency report was sent that Theranos began calling Yamamoto's office with procedural questions. It was Holmes, King, and Balwani that were calling. At this point in time, Theranos realized that they needed a new laboratory director. At one point, this new laboratory director was calling them on behalf of the laboratory asking questions about the CMS report. Dr. Dhawan was the laboratory director who "wasn't in the right position" at the time of the survey; he wasn't the new laboratory director hired after the deficiency report. He was there at the beginning part of the survey during the first two hours, and then they never saw him again.

Theranos had concerns over FOIA requests and the release of documents. Toward the end of the first week, Karen Fuller, Yamamoto's manager, was at Theranos and they discussed disclosure then. He thinks there were requests for a redacted deficiency report and he thinks that went through the FOIA process. Yamamoto thinks that after the second submission it was clear that Theranos didn't possess the documentation that CMS was seeking. Yamamoto said, "More than FOIA, it was just a bad laboratory." Yamamoto doesn't know if blaming the first inadequate response based on FOIA concerns was an authentic reason by Theranos.

At a certain point, Yamamoto was not part of the determination of what actions CMS took relating to the Theranos CLIA certificate. In all cases, the processes, remediation, and sanctions are the same. That wasn't unique in this case. The amount of time the process takes has to do with the size of the report, whether extensions are granted, etc. What actions CMS can take is somewhat discretionary, but any actions after revocation are statutorily prescribed. Yamamoto's role is to do the survey and issue the report. He determines whether the company's response is credible or not. At that point, the process is to propose sanctions to encourage the laboratory to come into compliance. Yamamoto drafted the second document that said Theranos's first response was insufficient. The sanctions they recommended were consistent with sanctions they would recommend to any other laboratory. Bennett and Yamamoto reviewed the second submission and found it not to be credible, so at that point CMS imposed the sanctions that they had proposed. CMS has some discretion as to whether they imposed the maximum possible sanctions. At this point, Yamamoto was somewhat out of this loop after he made a technical decision about their submission. A lot of people within CMS were involved in this because of the media attention, and he was not part of all those conversations about what was done at this point.

The individuals who were the owners and directors of Theranos at the time of this survey were prohibited from running a laboratory for a two-year period. Theranos relinquished their CLIA certificate. All the basic remedies available to CMS were basically finalized. It's Yamamoto's understanding that the sanctions imposed were never finalized by CMS, because CMS entered into an agreement with Theranos. Yamamoto was not a part of that process. The essence of what was in the agreement pretty much matched the essence of the proposed sanctions.

Generally, labs with bad business practices have bad quality. In the spectrum of laboratories in terms of laboratory results, Yamamoto doesn't think Theranos was trying to defraud anyone in terms of billing. In terms of the quality of the test results--it wasn't good. He wouldn't consider them the worst laboratory he's ever seen, but clearly they were far from the best. There was a fear, especially with coagulation testing, that people weren't getting the care they needed. CMS didn't see actual patient harm with Theranos. Clearly, nobody argued against them that the potential for harm was there.

Typically, during surveys a manager follows the surveyors around. The bigger the laboratory, the bigger the entourage.

SUBMITTED: Electronically submitted by GEORGE SCAVDIS

GEORGE SCAVDIS, SPECIAL AGENT DATE: 01/11/2018

APPROVED: Electronically approved by MARK MCCORMACK

MARK MCCORMACK, SPECIAL AGENT IN CHARGE DATE: 01/12/2018

DISTRIBUTION: Orig: MWFO
cc: Prosecution

ATTACHMENTS: None.

EXHIBIT 38

From: McDowell, Amanda
Sent: Tuesday, January 21, 2020 9:25 AM
To: Cygnor, Jennifer
Subject: FW: SEC v Balwani: Yamamoto Transcript
Attachments: Deposition Transcript 12-06-2019 - Pages 311 and 312.pdf; 2019-12 Yamamoto deposition transcript - OGC errata.pdf

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From: Mohan, Sharanya (USACAN) <Sharanya.Mohan@usdoj.gov>
Sent: Monday, January 20, 2020 6:51 PM
To: Cazares, Stephen <scazares@orrick.com>; Hefty, Andrew <heftya@SEC.GOV>; McDowell, Amanda <amcdowell@orrick.com>; Linsenmayer, Robin A. <rlinsenmayer@orrick.com>
Cc: Jenny, Brenna (HHS/OGC) <Brenna.Jenny@hhs.gov>; Clark, Tamara (OS/OGC) <Tamara.Clark@hhs.gov>; Turner, Lindsay (HHS/OGC) <Lindsay.Turner@hhs.gov>; Kasameyer, Katherine (OS/OGC) <Katherine.Kasameyer@hhs.gov>; Katz, Marc <katzma@SEC.GOV>; Han, John K <hanjo@SEC.GOV>; Samples, Wes (USACAN) <Wes.Samples@usdoj.gov>
Subject: RE: SEC v Balwani: Yamamoto Transcript

All,

Please find attached copies of (1) Mr. Yamamoto's errata and signature pages, and (2) an additional sheet containing errata from HHS OGC concerning the list of appearances.

Please let us know if you need anything further.

Thank you,
Sai

From: Cazares, Stephen <scazares@orrick.com>
Sent: Wednesday, December 18, 2019 7:40 PM
To: Hefty, Andrew <heftya@SEC.GOV>; Mohan, Sharanya (USACAN) <SMohan@usa.doj.gov>; McDowell, Amanda <amcdowell@orrick.com>; Linsenmayer, Robin A. <rlinsenmayer@orrick.com>
Cc: Jenny, Brenna (HHS/OGC) <Brenna.Jenny@hhs.gov>; Clark, Tamara (OS/OGC) <Tamara.Clark@hhs.gov>; Turner, Lindsay (HHS/OGC) <Lindsay.Turner@hhs.gov>; Kasameyer, Katherine (OS/OGC) <Katherine.Kasameyer@hhs.gov>; Katz, Marc <katzma@SEC.GOV>; Han, John K <hanjo@SEC.GOV>; Daw, Alison (USACAN) <ADaw@usa.doj.gov>
Subject: RE: SEC v Balwani: Yamamoto Transcript

Yes.

orrick

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From: Hefty, Andrew <heftya@SEC.GOV>
Sent: Wednesday, December 18, 2019 3:23 PM
To: Mohan, Sharanya (USACAN) <Sharanya.Mohan@usdoj.gov>; Cazares, Stephen <scazares@orrick.com>; McDowell, Amanda <amcdowell@orrick.com>; Linsenmayer, Robin A. <rlinsenmayer@orrick.com>
Cc: Jenny, Brenna (HHS/OGC) <Brenna.Jenny@hhs.gov>; Clark, Tamara (OS/OGC) <Tamara.Clark@hhs.gov>; Turner, Lindsay (HHS/OGC) <Lindsay.Turner@hhs.gov>; Kasameyer, Katherine (OS/OGC) <Katherine.Kasameyer@hhs.gov>; Katz, Marc <katzma@SEC.GOV>; Han, John K <hanjo@SEC.GOV>; Daw, Alison (USACAN) <Alison.Daw@usdoj.gov>
Subject: RE: SEC v Balwani: Yamamoto Transcript

Yes, the SEC is fine with that.

From: Mohan, Sharanya (USACAN) <Sharanya.Mohan@usdoj.gov>
Sent: Wednesday, December 18, 2019 2:16 PM
To: Hefty, Andrew <heftya@SEC.GOV>; Cazares, Stephen <scazares@orrick.com>; McDowell, Amanda <amcdowell@orrick.com>; Linsenmayer, Robin A. <rlinsenmayer@orrick.com>
Cc: Jenny, Brenna (HHS/OGC) <Brenna.Jenny@hhs.gov>; Clark, Tamara (OS/OGC) <Tamara.Clark@hhs.gov>; Turner, Lindsay (HHS/OGC) <Lindsay.Turner@hhs.gov>; Kasameyer, Katherine (OS/OGC) <Katherine.Kasameyer@hhs.gov>; Katz, Marc <katzma@SEC.GOV>; Han, John K <hanjo@SEC.GOV>; Daw, Alison (USACAN) <Alison.Daw@usdoj.gov>
Subject: RE: SEC v Balwani: Yamamoto Transcript

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Great, thanks everyone. We will have Mr. Yamamoto review the certified copy. I believe the deadline for him to do so is 30 days from my receipt of the copy, or January 10. Given the holidays, can he have two more weeks, until January 24, to provide any errata?

Thanks,
Sai

Sharanya Sai Mohan
Assistant United States Attorney
Northern District of California
450 Golden Gate Avenue
San Francisco, CA 94102
[redacted]
sharanya.mohan@usdoj.gov

From: Hefty, Andrew <heftya@SEC.GOV>
Sent: Wednesday, December 18, 2019 8:59 AM
To: Cazares, Stephen <scazares@orrick.com>; Mohan, Sharanya (USACAN) <SMohan@usa.doj.gov>; McDowell, Amanda <amcdowell@orrick.com>; Linsenmayer, Robin A. <rlinsenmayer@orrick.com>
Cc: Jenny, Brenna (HHS/OGC) <Brenna.Jenny@hhs.gov>; Clark, Tamara (OS/OGC) <Tamara.Clark@hhs.gov>; Turner, Lindsay (HHS/OGC) <Lindsay.Turner@hhs.gov>; Kasameyer, Katherine (OS/OGC) <Katherine.Kasameyer@hhs.gov>; Katz,

Marc <katzma@SEC.GOV>; Han, John K <hanjo@SEC.GOV>; Daw, Alison (USACAN) <ADaw@usa.doj.gov>
Subject: RE: SEC v Balwani: Yamamoto Transcript

No objection from the SEC.

From: Cazares, Stephen <scazares@orrick.com>
Sent: Tuesday, December 17, 2019 4:27 PM
To: Mohan, Sharanya (USACAN) <Sharanya.Mohan@usdoj.gov>; McDowell, Amanda <amcdowell@orrick.com>; Linsenmayer, Robin A. <rlinsenmayer@orrick.com>
Cc: Jenny, Brenna (HHS/OGC) <Brenna.Jenny@hhs.gov>; Clark, Tamara (OS/OGC) <Tamara.Clark@hhs.gov>; Turner, Lindsay (HHS/OGC) <Lindsay.Turner@hhs.gov>; Kasameyer, Katherine (OS/OGC) <Katherine.Kasameyer@hhs.gov>; Hefty, Andrew <heftya@SEC.GOV>; Katz, Marc <katzma@SEC.GOV>; Han, John K <hanjo@SEC.GOV>; Daw, Alison (USACAN) <Alison.Daw@usdoj.gov>
Subject: RE: SEC v Balwani: Yamamoto Transcript

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No objection from Mr. Balwani.

orrick

STEPHEN A. CAZARES
Of Counsel

ORRICK HERRINGTON & SUTCLIFFE LLP
777 South Figueroa Street, Suite 3200
Los Angeles, CA 90017

405 Howard Street
San Francisco, CA 94105

[redacted]
Scazares@Orrick.com

From: Mohan, Sharanya (USACAN) <Sharanya.Mohan@usdoj.gov>
Sent: Tuesday, December 17, 2019 4:25 PM
To: Cazares, Stephen <scazares@orrick.com>; McDowell, Amanda <amcdowell@orrick.com>; Linsenmayer, Robin A. <rlinsenmayer@orrick.com>
Cc: Jenny, Brenna (HHS/OGC) <Brenna.Jenny@hhs.gov>; Clark, Tamara (OS/OGC) <Tamara.Clark@hhs.gov>; Turner, Lindsay (HHS/OGC) <Lindsay.Turner@hhs.gov>; Kasameyer, Katherine (OS/OGC) <Katherine.Kasameyer@hhs.gov>; heftya@sec.gov; Katz, Marc <katzma@SEC.GOV>; Han, John K <hanjo@SEC.GOV>; Daw, Alison (USACAN) <Alison.Daw@usdoj.gov>
Subject: RE: SEC v Balwani: Yamamoto Transcript

No problem, thanks. We did order a certified copy. Would any of the parties object to Mr. Yamamoto noting any errata and signing the certified copy, as opposed to the original?

Thanks,
Sai

Sharanya Sai Mohan

Assistant United States Attorney
Northern District of California
450 Golden Gate Avenue
San Francisco, CA 94102
[redacted]
sharanya.mohan@usdoj.gov

From: Cazares, Stephen <scazares@orrick.com>
Sent: Tuesday, December 17, 2019 12:32 PM
To: Mohan, Sharanya (USACAN) <SMohan@usa.doj.gov>; McDowell, Amanda <amcdowell@orrick.com>; Linsenmayer, Robin A. <rlinsenmayer@orrick.com>
Cc: Jenny, Brenna (HHS/OGC) <Brenna.Jenny@hhs.gov>; Clark, Tamara (OS/OGC) <Tamara.Clark@hhs.gov>; Turner, Lindsay (HHS/OGC) <Lindsay.Turner@hhs.gov>; Kasameyer, Katherine (OS/OGC) <Katherine.Kasameyer@hhs.gov>; heftya@sec.gov; Katz, Marc <katzma@SEC.GOV>; Han, John K <hanjo@SEC.GOV>; Daw, Alison (USACAN) <ADaw@usa.doj.gov>
Subject: RE: SEC v Balwani: Yamamoto Transcript

Sai,

So sorry. This got lost in the shuffle. We were confused as we thought we heard Alison order a copy of the transcript from the reporter. Are you saying that CMS has not/will not be ordering a copy and that Mr. Yamamoto needs a copy to complete the Errata Sheet if applicable?

orrick

STEPHEN A. CAZARES
Of Counsel

ORRICK HERRINGTON & SUTCLIFFE LLP
777 South Figueroa Street, Suite 3200
Los Angeles, CA 90017

405 Howard Street
San Francisco, CA 94105

[redacted]
Scazares@Orrick.com

From: Mohan, Sharanya (USACAN) <Sharanya.Mohan@usdoj.gov>
Sent: Tuesday, December 17, 2019 12:24 PM
To: McDowell, Amanda <amcdowell@orrick.com>; Cazares, Stephen <scazares@orrick.com>; Linsenmayer, Robin A. <rlinsenmayer@orrick.com>
Cc: Jenny, Brenna (HHS/OGC) <Brenna.Jenny@hhs.gov>; Clark, Tamara (OS/OGC) <Tamara.Clark@hhs.gov>; Turner, Lindsay (HHS/OGC) <Lindsay.Turner@hhs.gov>; Kasameyer, Katherine (OS/OGC) <Katherine.Kasameyer@hhs.gov>; heftya@sec.gov; Katz, Marc <katzma@SEC.GOV>; Han, John K <hanjo@SEC.GOV>; Daw, Alison (USACAN) <Alison.Daw@usdoj.gov>
Subject: RE: SEC v Balwani: Yamamoto Transcript

Hi,

I am following up on my email below regarding the original transcript.

Thanks,
Sai

Sharanya Sai Mohan
Assistant United States Attorney
Northern District of California
450 Golden Gate Avenue
San Francisco, CA 94102
[redacted]
sharanya.mohan@usdoj.gov

From: Mohan, Sharanya (USACAN)
Sent: Thursday, December 12, 2019 12:42 PM
To: McDowell, Amanda <amcdowell@orrick.com>; Cazares, Stephen <scazares@orrick.com>; rlinsenmayer@orrick.com
Cc: Jenny, Brenna (HHS/OGC) <Brenna.Jenny@hhs.gov>; Clark, Tamara (OS/OGC) <Tamara.Clark@hhs.gov>; Turner, Lindsay (HHS/OGC) <Lindsay.Turner@hhs.gov>; Kasameyer, Katherine (OS/OGC) <Katherine.Kasameyer@hhs.gov>; heftya@sec.gov; Katz, Marc <katzma@SEC.GOV>; Han, John K <hanjo@SEC.GOV>; Alison Daw (USACAN) (ADaw@usa.doj.gov) <ADaw@usa.doj.gov>
Subject: SEC v Balwani: Yamamoto Transcript

Good afternoon,

Will the defendant be providing the original of Mr. Yamamoto's deposition transcript to CMS for him to review?

Thanks,
Sai

Sharanya Sai Mohan
Assistant United States Attorney
Northern District of California
450 Golden Gate Avenue
San Francisco, CA 94102
[redacted]
sharanya.mohan@usdoj.gov

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DECLARATION UNDER PENALTY OF PERJURY

I, Gary Yamamoto, do hereby certify under penalty of perjury that I have reviewed the foregoing transcript of my deposition taken on December 6, 2019; that I have made such corrections as appear noted herein in ink; that my testimony as contained herein, as corrected, is true and correct.

DATED this 16 day of JANUARY, 2020, at San Francisco, California.

Gary Yamamoto

ERRATA SHEET

Printed Name Gary Yamamoto Date 01/16/2020

Signature

Page/Line	Correction	Reason
48/2	and do → under	CLARITY
48/3	nature → ageney	CLARITY
50/19	its attention → the country	CLARITY
53/9	conditional → condition	CLARITY
53/12	conditioned → condition	CLARITY
56/6	we make → would make	CLARITY
57/8	they'll recite → review	CLARITY
114/6	workman → workload	CLARITY
151/21	Perdan → Prodan	MISSPELLING
158/5	Faria → Ferrier	MISSPELLING
158/13	Faria → Ferrier	MISSPELLING

ERRATA SHEET

Printed Name Tamara S. Clark Date 1/16/2020

Signature

Page/Line	Correction	Reason
5/5	strike General Counsel / Add Attorney	Correct title
5/7	strike 801 Market Street, Suite 9700	
	Philadelphia, Pennsylvania 19107	
	Add 200 Independence Ave, S.W.	Correct Address
	Washington, DC 20201	
5/8	strike 215-861-4456	
	Add 202-690-7740	correct phone number

EXHIBIT 39

From: McDowell, Amanda
Sent: Monday, March 23, 2020 12:37 PM
To: Cygnor, Jennifer
Cc: Cazares, Stephen
Subject: FW: CMS deposition errata
Attachments: Yamamoto - Signed Errata.pdf; Dyer - Signed Errata.pdf; Bennett - Signed Errata.pdf

---

From: Mohan, Sharanya (USACAN)
Sent: Monday, March 23, 2020 12:35 PM
To: Samples, Wes (USACAN) ; Coopersmith, Jeffrey ; LaMarca, Susan F. ; McDowell, Amanda ; Katz, Marc ; production@centextlegal.com; Cazares, Stephen
Subject: CMS deposition errata

All,

Attached are the errata for the CMS witnesses, including Mr. Yamamoto's (previously sent) for completeness. Please note that Ms. Bennett's transcript had some odd numbering, requiring her to identify the time stamp of each relevant line in the errata, and some pages unfortunately have the same time stamp and line number pairing in multiple places. If any of the notations are confusing, please let us know.

Thank you,

Sai

Sharanya Sai Mohan
Assistant United States Attorney
Northern District of California
450 Golden Gate Avenue
San Francisco, CA 94102
[redacted]
sharanya.mohan@usdoj.gov

From: Samples, Wes (USACAN) <WSamples@usa.doj.gov>
Sent: Monday, March 16, 2020 1:20 PM
To: Coopersmith, Jeffrey <jcoopersmith@orrick.com>; LaMarca, Susan F. <LAMARCAS@sec.gov>; McDowell, Amanda <amcdowell@orrick.com>; Katz, Marc <katzma@SEC.GOV>; production@centextlegal.com
Cc: Mohan, Sharanya (USACAN) <SMohan@usa.doj.gov>
Subject: RE: FDA deposition errata

All,

Pursuant to the below please find the errata and signature pages for seven of the eight FDA witnesses (the eighth being Dr. Gutierrez). The attached zip file is password protected. The password will be sent in a second email to follow immediately hereafter.

Please don't hesitate to contact me if you have any trouble accessing the attached.

Thanks,
Wes

Wes Samples
Assistant United States Attorney
United States Attorney's Office, Northern District of California
450 Golden Gate Avenue
Box 36055
San Francisco, CA 94102
[redacted]
wes.samples@usdoj.gov

From: Coopersmith, Jeffrey <jcoopersmith@orrick.com>
Sent: Friday, March 13, 2020 4:36 PM
To: LaMarca, Susan F. <LAMARCAS@sec.gov>; Samples, Wes (USACAN) <WSamples@usa.doj.gov>; McDowell, Amanda <amcdowell@orrick.com>; Katz, Marc <katzma@SEC.GOV>; Mohan, Sharanya (USACAN) <SMohan@usa.doj.gov>
Cc: Hefty, Andrew <heftya@SEC.GOV>; 'Norton, Marci' <Marci.Norton@fda.hhs.gov>; Dacuag, Evelyn <edacuag@orrick.com>; 'Turner, Lindsay (OS)' <Lindsay.Turner@hhs.gov>; Kolhatkar, Rahul <kolhatkarr@SEC.GOV>; 'MartinezResly, Jaclyn' <Jaclyn.MartinezResly@fda.hhs.gov>; 'DiPaola, Lauren' <Lauren.Dipaola@fda.hhs.gov>; Linsenmayer, Robin A. <rlinsenmayer@orrick.com>; Cazares, Stephen <scazares@orrick.com>; 'Heller, Seth' <Seth.Heller@fda.hhs.gov>; 'Lovas, Julie' <Julie.Lovas@fda.hhs.gov>; 'Perham.Gorji@fda.hhs.gov' <Perham.Gorji@fda.hhs.gov>; Cygnor, Jennifer <jcygnor@orrick.com>; Patts, Lenny <lpatts@orrick.com>; Dacuag, Evelyn <edacuag@orrick.com>
Subject: RE: FDA deposition errata

I agree as well on behalf of Mr. Balwani. We also second Suzy's best wishes for Dr. Gutierrez's recovery.

Best,

orrick

JEFFREY B. COOPERSMITH
Partner

ORRICK HERRINGTON & SUTCLIFFE LLP
701 Fifth Avenue, Suite 5600
Seattle, WA 98104

405 Howard Street
San Francisco, CA 94105

[redacted]
jcoopersmith@orrick.com
Admitted in Washington, California, and the District of Columbia

From: LaMarca, Susan F. <LAMARCAS@sec.gov>
Sent: Friday, March 13, 2020 4:24 PM
To: Samples, Wes (USACAN) <Wes.Samples@usdoj.gov>; McDowell, Amanda <amcdowell@orrick.com>; Katz, Marc <katzma@SEC.GOV>; Mohan, Sharanya (USACAN) <Sharanya.Mohan@usdoj.gov>
Cc: Hefty, Andrew <heftya@SEC.GOV>; 'Norton, Marci' <Marci.Norton@fda.hhs.gov>; Dacuag, Evelyn <edacuag@orrick.com>; 'Turner, Lindsay (OS)' <Lindsay.Turner@hhs.gov>; Kolhatkar, Rahul <kolhatkarr@SEC.GOV>; 'MartinezResly, Jaclyn' <Jaclyn.MartinezResly@fda.hhs.gov>; 'DiPaola, Lauren' <Lauren.Dipaola@fda.hhs.gov>; Coopersmith, Jeffrey <jcoopersmith@orrick.com>; Linsenmayer, Robin A. <rlinsenmayer@orrick.com>; Cazares, Stephen <scazares@orrick.com>; 'Heller, Seth' <Seth.Heller@fda.hhs.gov>; 'Lovas, Julie' <Julie.Lovas@fda.hhs.gov>; 'Perham.Gorji@fda.hhs.gov' <Perham.Gorji@fda.hhs.gov>
Subject: RE: FDA deposition errata

The SEC agrees. (Hope he recovers quickly!)

Suzy

SUSAN F. LAMARCA
U.S. SECURITIES AND EXCHANGE COMMISSION
Regional Trial Counsel
San Francisco Regional Office
44 Montgomery Street, Suite 2800 | San Francisco, CA 94104
[redacted] | lamarcas@sec.gov

From: Samples, Wes (USACAN) <Wes.Samples@usdoj.gov>
Sent: Friday, March 13, 2020 3:39 PM
To: McDowell, Amanda <amcdowell@orrick.com>; Katz, Marc <katzma@SEC.GOV>; Mohan, Sharanya (USACAN) <Sharanya.Mohan@usdoj.gov>
Cc: Hefty, Andrew <heftya@SEC.GOV>; LaMarca, Susan F. <LAMARCAS@sec.gov>; 'Norton, Marci' <Marci.Norton@fda.hhs.gov>; Dacuag, Evelyn <edacuag@orrick.com>; 'Turner, Lindsay (OS)' <Lindsay.Turner@hhs.gov>; Kolhatkar, Rahul <kolhatkarr@SEC.GOV>; 'MartinezResly, Jaclyn' <Jaclyn.MartinezResly@fda.hhs.gov>; 'DiPaola, Lauren' <Lauren.Dipaola@fda.hhs.gov>; Coopersmith, Jeffrey <jcoopersmith@orrick.com>; Linsenmayer, Robin A. <rlinsenmayer@orrick.com>; Cazares, Stephen <scazares@orrick.com>; 'Heller, Seth' <Seth.Heller@fda.hhs.gov>; 'Lovas, Julie' <Julie.Lovas@fda.hhs.gov>; 'Perham.Gorji@fda.hhs.gov' <Perham.Gorji@fda.hhs.gov>
Subject: RE: FDA deposition errata

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Hi all,

I write regarding Dr. Gutierrez's deposition errata and signature page. I understand that Dr. Gutierrez is currently ill. Accordingly, FDA is requesting a three week extension for Dr. Gutierrez's deposition errata and signature page, until April 13, 2020, to allow him to recover and thereafter review his transcript. FDA expects that the deposition errata and signature pages for the other FDA witnesses will be provided timely pursuant to the parties below agreement.

Please confirm when you have a moment.

Thank you,
Wes

Wes Samples
Assistant United States Attorney
United States Attorney's Office, Northern District of California
450 Golden Gate Avenue
Box 36055
San Francisco, CA 94102
[redacted]
wes.samples@usdoj.gov

From: McDowell, Amanda <amcdowell@orrick.com>
Sent: Wednesday, February 5, 2020 10:13 AM
To: Katz, Marc <katzma@SEC.GOV>; Mohan, Sharanya (USACAN) <SMohan@usa.doj.gov>
Cc: Hefty, Andrew <heftya@SEC.GOV>; Samples, Wes (USACAN) <WSamples@usa.doj.gov>; LaMarca, Susan F. <LAMARCAS@sec.gov>; 'Norton, Marci' <Marci.Norton@fda.hhs.gov>; Dacuag, Evelyn <edacuag@orrick.com>; 'Turner, Lindsay (OS)' <Lindsay.Turner@hhs.gov>; Kolhatkar, Rahul <kolhatkarr@SEC.GOV>; 'MartinezResly, Jaclyn' <Jaclyn.MartinezResly@fda.hhs.gov>; 'DiPaola, Lauren' <Lauren.Dipaola@fda.hhs.gov>; Coopersmith, Jeffrey <jcoopersmith@orrick.com>; Linsenmayer, Robin A. <rlinsenmayer@orrick.com>; Cazares, Stephen <scazares@orrick.com>; 'Heller, Seth' <Seth.Heller@fda.hhs.gov>; 'Lovas, Julie' <Julie.Lovas@fda.hhs.gov>; 'Perham.Gorji@fda.hhs.gov' <Perham.Gorji@fda.hhs.gov>
Subject: RE: FDA deposition errata

For Mr. Balwani, we are also fine with this.

Thanks,

Amanda

orrick
AMANDA M. MCDOWELL
Managing Associate
ORRICK HERRINGTON & SUTCLIFFE LLP
701 Fifth Avenue, Suite 5600
Seattle, WA 98104
[redacted]

From: Katz, Marc <katzma@SEC.GOV>
Sent: Wednesday, February 5, 2020 9:20 AM
To: Mohan, Sharanya (USACAN) <Sharanya.Mohan@usdoj.gov>; McDowell, Amanda <amcdowell@orrick.com>
Cc: Hefty, Andrew <heftya@SEC.GOV>; Samples, Wes (USACAN) <Wes.Samples@usdoj.gov>; LaMarca, Susan F. <LAMARCAS@sec.gov>; 'Norton, Marci' <Marci.Norton@fda.hhs.gov>; Dacuag, Evelyn <edacuag@orrick.com>; 'Turner,

Lindsay (OS)' <Lindsay.Turner@hhs.gov>; Kolhatkar, Rahul <kolhatkarr@SEC.GOV>; 'MartinezResly, Jaclyn' <Jaclyn.MartinezResly@fda.hhs.gov>; 'DiPaola, Lauren' <Lauren.Dipaola@fda.hhs.gov>; Coopersmith, Jeffrey <jcoopersmith@orrick.com>; Linsenmayer, Robin A. <rlinsenmayer@orrick.com>; Cazares, Stephen <scazares@orrick.com>; 'Heller, Seth' <Seth.Heller@fda.hhs.gov>; 'Lovas, Julie' <Julie.Lovas@fda.hhs.gov>; 'Perham.Gorji@fda.hhs.gov' <Perham.Gorji@fda.hhs.gov>
Subject: RE: FDA deposition errata

The SEC is fine with your proposal, Sai.

Thank you.
-Marc

Marc Katz
U.S. Securities & Exchange Commission
44 Montgomery Street, Suite 2800
San Francisco, CA 94104
[redacted]
katzma@sec.gov

From: Mohan, Sharanya (USACAN) <Sharanya.Mohan@usdoj.gov>
Sent: Wednesday, February 5, 2020 8:21 AM
To: 'McDowell, Amanda' <amcdowell@orrick.com>
Cc: Hefty, Andrew <heftya@SEC.GOV>; Samples, Wes (USACAN) <Wes.Samples@usdoj.gov>; LaMarca, Susan F. <LAMARCAS@sec.gov>; 'Norton, Marci' <Marci.Norton@fda.hhs.gov>; 'Dacuag, Evelyn' <edacuag@orrick.com>; 'Turner, Lindsay (OS)' <Lindsay.Turner@hhs.gov>; Kolhatkar, Rahul <kolhatkarr@SEC.GOV>; 'MartinezResly, Jaclyn' <Jaclyn.MartinezResly@fda.hhs.gov>; Katz, Marc <katzma@SEC.GOV>; 'DiPaola, Lauren' <Lauren.Dipaola@fda.hhs.gov>; 'Coopersmith, Jeffrey' <jcoopersmith@orrick.com>; 'Linsenmayer, Robin A.' <rlinsenmayer@orrick.com>; 'Cazares, Stephen' <scazares@orrick.com>; 'Heller, Seth' <Seth.Heller@fda.hhs.gov>; 'Lovas, Julie' <Julie.Lovas@fda.hhs.gov>; 'Perham.Gorji@fda.hhs.gov' <Perham.Gorji@fda.hhs.gov>
Subject: FDA deposition errata

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All,

Hope you had safe travels back last week. We are starting to get the transcript copies for the depositions of the FDA current and former witnesses, and we were hoping the parties would agree to the following regarding the errata, with the goal of simplifying this process:

(1) All of the FDA witnesses can review and sign the certified copies, rather than the originals, of the transcripts.
(2) All of the FDA witnesses' errata and signature pages are due 45 days from today.

Please confirm when you have a chance.

Thanks,
Sai

Sharanya Sai Mohan
Assistant United States Attorney
Northern District of California
450 Golden Gate Avenue
San Francisco, CA 94102
[redacted]
sharanya.mohan@usdoj.gov

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DECLARATION UNDER PENALTY OF PERJURY

I, Gary Yamamoto, do hereby certify under penalty of perjury that I have reviewed the foregoing transcript of my deposition taken on December 6, 2019; that I have made such corrections as appear noted herein in ink; that my testimony as contained herein, as corrected, is true and correct.

DATED this 16 day of JANUARY, 2020, at San Francisco, California.

Gary Yamamoto

ERRATA SHEET

Printed Name Gary Yamamoto Date 01/16/2020

Signature

Page/Line	Correction	Reason
48/2	and do → under	CLARITY
48/3	nature → ageney	CLARITY
50/19	its attention → the Country	CLARITY
53/9	conditional → condition	CLARITY
53/12	conditioned → condition	CLARITY
56/6	we make → would make	CLARITY
57/8	they'll recite → review	CLARITY
114/6	workman → workload	CLARITY
151/21	Perdan → Prodan	MISSPELLING
158/5	Faria → Ferrier	MISSPELLING
158/13	Faria → Ferrier	MISSPELLING

CERTIFICATE OF DEPONENT

I hereby certify that I have read and examined the foregoing transcript, and the same is a true and accurate record of the testimony given by me.

Any additions or corrections that I feel are necessary will be made on the Errata Sheet.

Karen W. Dyer -S

Digitally signed by Karen W. Dyer -S
Date: 2020.03.17 12:10:26 -04'00'

Karen Dyer

Date

(If needed, make additional copies of the Errata Sheet on the next page or use a blank piece of paper.)

ERRATA SHEET

Case: SEC V Ramesh "Sunny" Balwani

Witness: Karen Dyer Date: 01/28/2020

PAGE/LINE	SHOULD READ	REASON FOR CHANGE
11/25	Baltimore County on a night shift in a stat laboratory.	correct transcription error
116/17	the accrediting org -- accrediting organization	correct transcription error
160/7	very uncomfortable, a little apprehensive about being	correct transcription error
170/12	kind of project relating to IQCP	correct transcription error
170/21	And IQCP relates to what?	correct transcription error
185/8	The first one 493.801 is the condition	correct transcription error
185/18	I do not remember without my regulation book	correct transcription error
204/1	moderate complex lab. No nanotainers, no TSPU, no	correct transcription error

CERTIFICATE OF DEPONENT

I hereby certify that I have read and examined the foregoing transcript, and the same is a true and accurate record of the testimony given by me.

Any additions or corrections that I feel are necessary will be made on the Errata Sheet.

_____

Sarah Bennett

_____

Date

(If needed, make additional copies of the Errata Sheet on the next page or use a blank piece of paper.)

ERRATA SHEET

Case: SEC V Ramesh "Sunny" Balwani

Witness: Sarah Bennett Date: 01/29/2020

PAGE/LINE	SHOULD READ	REASON FOR CHANGE
14/8:43-8:44/4-5	purchased from manufacturers and are being used the way that the manufacturer -- so when we see	correct transcript language
16/8:45/3	That's important because	correct transcript language
18/8:48/0	usually received and logged in so that	correct transcript language
21/8:51/3-5	what we would do. We would request documents or we could go back into the lab and look at specific areas	correct transcript language
24/8:55/2-4	Generally if there is more than one surveyor -- in my experience that's how it worked that we	clarify transcript language
27/9:01/1	there the first or the second -- came the first or the	clarify transcript language
30/9:04/5	laboratory and issues we may find when we're on	correct transcript language
32/9:07/1-5	We conduct those interviews to find out how the laboratory's daily workload is, how they perform testing, how they perform quality control. If we have a compliance issue, we will ask them to confirm what we've found	clarify transcript language
39/9:18/2	we were all let go. We could stay or we	clarify transcript language
45/9:26/3-4	talk to me about the regulations, they will call me, in Baltimore, like I said, the regional offices is	correct transcript language
49/9:33/5-6	What I meant was that if it was between me and an attorney, my	correct transcript language
50/9:35/6-7	I believe that the requests all came in writing	correct transcript language
68/10:16/7	laboratory's ability to meet the CLIA requirements	correct transcript language
76/10:27/9-0	--or at least the ones that we were given names for.	correct transcript language
83/10:37/8	event of 2015 from the College of American	correct transcript language
120/11:42/3	validating the analytes.	correct transcript language
127/11:54/9-0	This is a reference to the proprietary Edison device.	correct transcript language
136/12:55/2	I don't recall.	clarify transcript language
155/1:23/14	regulatory requirement at 493.851(e). That's an	correct transcript language
177/2:10/14	run on 9/18/15, September 18th, 2015	correct transcript language
197/2:50/22	I didn't have any contact with Ellen Gabler	correct transcript language

EXHIBIT 40

MEMORANDUM OF INTERVIEW

CASE NUMBER	:	2204323-MF
PERSON INTERVIEWED	:	Dr. Kingshuk Das
PLACE OF INTERVIEW	:	Videoconference Call
DATE OF INTERVIEW	:	November 5, 2021
TIME OF INTERVIEW	:	2:00 P.M.

On November 5, 2021, Dr. Kingshuk Das (DAS) was interviewed by videoconference call in preparation for possible trial testimony. Assistant United States Attorneys Robert Leach and John Bostic conducted the interview. Food and Drug Administration-Office of Criminal Investigation Special Agent George Scavdis was also present. Dan Roth was present as DAS' counsel. Prior to the start of the interview, AUSA Leach explained the testimony process and other general courtroom procedures. The following is a summary of the statements made during the interview.

DAS saw a job posting for a position at Theranos and applied. At the time of his application, he was not familiar with the company. DAS had on-site interviews individually with Elizabeth Holmes (HOLMES), Sunny Balwani (BALWANI), Daniel Young (YOUNG), and one other individual. During the interview with HOLMES, she provided an overview of the company, discussed DAS' background, and talked about some of the regulatory issues Theranos faced. She also said Theranos needed a high-level lab directorship. DAS was offered the job as laboratory director and worked at Theranos part-time during his transition from his previous employment. During this time, he visited the lab one time per week and mainly reviewed paperwork.

DAS reviewed trial exhibit 5450 and said that while he is familiar with Dr. Sunil Dhawan and he is familiar with this type of document, he was not familiar with this particular document. As director, DAS was given a tour of Theranos' lab, viewed the instruments in use, and given a general overview of the company. DAS also reviewed documents from the CMS [Centers for Medicare and Medicaid Services] audit. Page three of the form (page five of the trial exhibit) lists testing specialties and annual test volumes. DAS was not aware Theranos conducted immunohematology assays, but said all other lab specialties and subspecialties were consistent with his memory. Additionally, DAS believed the annual test volume was consistent with Theranos' annual volume.

DAS was aware Theranos operated a moderate complexity CLIA lab in Arizona. As a moderate complexity lab, it could not run any LDTs [laboratory developed tests], or any other high complexity testing. Non-proprietary devices were used in Arizona. DAS believed the majority of Theranos' clinical lab testing took place in Arizona. He had no responsibility for that lab.

DAS reviewed trial exhibit 5453 and said he was not familiar with the document. DAS estimated Theranos ran approximately fifty to seventy LDTs in the lab, consisting of FDA approved assays that had been modified, internal Theranos assays, assays run on Theranos proprietary devices, and assays run on modified third-party devices.

DAS reviewed trial exhibit 5451 and said that while he had not seen this document before, he had seen something similar.

DAS reviewed trial exhibit 4533 and said the date written in the document which referenced the CMS audit seemed consistent with what he knew. The assays listed in this document were run on Edison 3.5 devices.

Lisa Helfend (HELFEND) was a contract lab director before DAS stated at Theranos. Don Tschihart (TSCHIHART) was co-director with DAS. Most assays had been stopped when DAS started at Theranos. He did not think the company ran any LDTs and was given no explanation as to why.

DAS had minimal involvement with BALWANI. He emailed HOLMES and met with her in-person when he was local.

DAS reviewed trial exhibit 4621 and said he knew it as the CMS deficiency report, something he was very familiar with. While still transitioning to full time, DAS conducted patient impact assessments for the deficiencies identified in the report with a team of people, including YOUNG, Tina Lin (LIN), TSCHIHART, David Zifkin (ZIFKIN), and Michelle Carbone (CARBONE). The goal of the impact assessment was to determine if a deficiency impacted a patient and if corrections needed to be made. The group worked through the findings, reviewed QC [quality control] data for all devices and methods, reviewed test result distributions, reviewed SOPs [standard operating procedures] associated with specific deficiencies, and developed plans to correct the identified issues. The review examined the QC data and test result distributions generated by the Edison 3.5 devices, too. DAS continued this work after he became a fulltime employee. He spent most of his work time addressing the CMS Form 2567. HOLMES was kept updated of the progress.

Patient impact assessments were finalized in pieces and multiple responses were submitted to CMS for the issues identified in the Form 2567. As a result of his investigation, DAS recommended all assay results generated by the Edison 3.5 devices should be voided as the devices were not suitable for patient use. DAS said all twelve assays run on the Edison suffered from the same deficiencies, namely issues with the validation methods, issues with proficiency testing, and issues with the distribution of test results. The validation method issues were conveyed to HOLMES and she was supportive of DAS' findings. While not resistant to voiding the Edison assays, HOLMES was initially resistant to the characterization of why the tests were voided. HOMES wanted the voiding of the tests attributed to issues with Theranos' quality systems, and not the devices themselves. DAS disagreed with her characterization and said all data supported his conclusion of issues with the devices.

DAS did not know if HOLMES reviewed the patient impact assessments.

DAS did not review the Edison validation reports, but rather excerpts from them. He asked for the full reports, probably from YOUNG, but was not given them and was never provided an explanation why. From what he had reviewed, none of the twelve Edison assays met the acceptance criteria requirements stated in the validation reports. These conclusions were supported by his review of the QC data and patient test distribution. He did not remember if HOLMES ever commented on this.

DAS conducted patient impact assessments as it was a required function of his position of laboratory director. He had a professional obligation to look for patient harm. DAS was familiar

with regulations to report which he said were standard for all labs. Patients and/or providers must be notified if test results are either voided or corrected. It would have been a violation of regulations to not provide notification if an issue was identified.

The decision to void certain tests was made sometime in March 2016. DAS initially said his decision to void the tests was voluntary, but clarified that it would have been incorrect to not do so. Based on his review of the data, it was necessary to void the tests. DAS was familiar with CLIA regulations but had worked more often under CAP regulations, which were CLIA deemed. If Theranos had not voided the tests as he recommended, the company would not have fulfilled its obligations under either CLIA or CAP.

HOLMES was told in a meeting about his decision to void the tests, and DAS felt what he believed was pushback during that meeting. HOLMES wanted to say the voiding of tests was due to a process issue, not a device issue. DAS believed HOLMES had a conversation, which he was not privy to, with a scientist that caused her to believe the issues were a result of quality systems issues. There was a letter sent to CMS about the voiding of tests. DAS disagreed with the language of the letter but not the overall result.

DAS never recommended Theranos restart Edison testing because the devices were not suitable for patient testing and the issues were not remediated.

DAS remembered a discussion he had with HOLMES regarding PSA [prostate specific antigen] related to his decision to void the Edison tests. He used the PSA assay as an example of the Edison device producing dangerous data and identified instances where females returned measurable PSA results. These results were unexpected, however, HOLMES referred him to an article where females who suffered from breast cancer had measurable PSA. DAS did not find this explanation credible.

DAS, HOLMES, TSCHIHART, and Heather King (KING) travelled to the Washington, D.C. area for an April meeting with CMS, including Sarah Bennett (BENNETT), Dr. [Kate] Goodrich (GOODRICH), and several her deputies. The purpose of the meeting was to meet with CMS leadership and to introduce Theranos' new lab directors to the agency. DAS believed the meeting went well.

DAS had previously said the deficiencies identified in the Form 2567 were just the "tip of the iceberg" of the issues at Theranos, and he still believed that was true. Based on the results of his investigation, DAS agreed with all findings identified by CMS. DAS did not believe Theranos had been singled-out unfairly for scrutiny. He did not know HOLMES' view of the matter. He did not remember if HOLMES ever complained that CMS had been pressured to act by the media.

DAS said his review resulted in a series of submissions to CMS. The investigation was never truly completed.

PT/INR tests were voided due to issues with how results were calculated, and with quality control and patient result distribution issues.

DAS reviewed document THPFM0004587299. The 1800 was an Advia device, and an accession was a test logged into the Theranos lab. DAS did not recall the context of this message. In an email from DAS to YOUNG, BALWANI, and others, he wrote, "I had a chance to touch base with Tina and Daniel the other day to get details on the updated patient impact assessments, and

I've decided to take a more conservative approach." Based on his review, DAS decided that if a sodium test, for example, was incorrect, that result should be acted upon regardless if other tests were affected. DAS did not remember specific discussions surrounding this issue.

DAS believed approximately 50K to 60K Edison assay tests were voided, as well as thousands to tens of thousands of LDTs run on the Advia 1800 across all analytes. DAS recommended all LDTs, comprising hundreds of thousands of tests, be voided based on reasons similar to that of the Edison. Namely, these tests suffered from unacceptable issues with quality control, proficiency testing, and the distribution of patient test results. However, DAS viewed the validation of these assays as acceptable.

The issues DAS identified with quality control, proficiency testing, and the distribution of patient test results spoke to continued vigilance of testing specifications, and that validation of an assay was simply not enough. Issues like those he saw at Theranos could be periodic and result from reagent or device issues. However, DAS said it was unusual to see the degree and length that these issues took hold at Theranos. This was the result of instrument issues, not just quality control.

In addition to the distribution of test results, DAS also reviewed test flags, such as normal versus abnormal results.

DAS reviewed document THPFM0004005447 and identified it as QC summary data from Edison assays. The values in the columns associated with specific assays were the number of failed QC results. "2SD" referred to a result two standard deviations from the mean. "10X" referred to a series of ten results on the same side of the mean. This was undesirable. "41S," which should have been more appropriately written "4-1S," referred to a series of four results one standard deviation away from the mean. This was undesirable. The information in this document was consistent with the information DAS had reviewed which lead him to void tests.

DAS reviewed document THPFM0003858517 and said he knew Larry Kricka (KRICKA) and believed he was on Theranos' Scientific and Medical Advisory Board. Theranos wanted opinions of the company's response to CMS. DAS did not remember if voiding of tests or the desire to characterize it as a quality systems issue was discussed with the advisory board. In the document, TSCHIHART and DAS recommended a CMS response to HOLMES that reflected their plans and thoughts.

DAS said the owner-operator of a clinical lab, and the laboratory director, had responsibility under CLIA regulations. To be responsible, the owner must have had at least a 5% stake in the lab, of which HOLMES did.

DAS did not attend HOLMES' presentation at the AACC [American Association for Clinical Chemistry] conference, nor did he provide any input to her presentation.

DAS did some work on a Zika test to be run on Theranos' minilab device, which he thought was a 5.0 series device. He did not know if the work was submitted to the FDA.

DAS "heard whispers" of an August 2015 FDA inspection.

DAS had minimal interaction with the Scientific and Medical Advisory Board. Some of the members were professors that had educated DAS. None of them made any comments to him of their time on the board.

DAS reviewed document THPFM0003858470 and said the "BUGS" lab was the internal nickname for the Newark microbiology lab. The lab ran several automated and manually operated devices. He did think the lab ran any LDTs. The document outlined a failed proficiency test, which DAS recalled. He could not remember when the failed test happened, however. The failed proficiency test triggered an investigation which uncovered an error in an SOP contrary to manufacturer recommendations. HIV assays can be either screening or diagnostic. The failed proficiency test was a diagnostic type.

DAS remained at Theranos until 2018. HOLMES was his direct supervisor for at least half of his tenure at the company.

DAS said automated reflex testing was not run on the Edison device, and he was not aware, and did not think, this type of testing was run on the Advia 1800 devices either.

There were no Theranos analyzers in the CLIA lab during DAS' tenure. There were some in the Normandy lab for purposes other than clinical testing.

DAS viewed the voiding of CBC assays as a simple decision because Theranos did not run any QC for these assays.

We took a break from 2:55 P.M. to 3:03 P.M.

The interview ended at 4:01 P.M.

Christopher McCollow

Christopher McCollow	November 6, 2021
US Postal Inspector	Date

Attachments:

Trial Exhibit 5450
Trial Exhibit 5453
Trial Exhibit 5451
Trial Exhibit 4533
Trial Exhibit 4621
THPFM0004587299
THPFM0004005447
THPFM0003858517
THPFM0003858470

EXHIBIT 41

(UNREDACTED EXHIBIT FILED UNDER SEAL)

U.S. Department of Justice

United States Attorney
Northern District of California

150 Almaden Boulevard, Suite 900 *(408) 535-5061*
San Jose, California 95113 *FAX:(408) 535-5066*

November 10, 2021

Jeffrey B. Coopersmith
Amy Walsh
Stephen Cazares
Orrick Herrington & Sutcliffe LLP
701 5th Avenue, Suite 5600
Seattle, WA 98104-7097
VIA Email

Re: United States v. Ramesh "Sunny" Balwani
CR-18-00258-EJD

Dear Counsel:

I write in response to your October 18, 2021, letter requesting additional disclosure of any co-conspirator statements the government intends to offer against Defendant Ramesh "Sunny" Balwani" under Federal Rule of Evidence 801(d)(2)(E).

On or about June 29, 2020, we provided you with our Local Rule 16-1(c)(1)-(4) disclosure in the *Holmes* matter. Your October 18, 2021 letter – sent during the *Holmes* trial – is the first we understood you sought greater disclosure about the co-conspirator statements the government may seek to admit in the *Balwani* trial.

We believe our June 26, 2020 notice is sufficient. In addition, you have had, on top of the notice, the benefit of (1) any early *Jencks* disclosure, including grand jury testimony, (2) extensive civil discovery from prior proceedings, and (3) the testimony in the *Holmes* trial. As you have seen in observing the ongoing *Holmes* trial, numerous documents on the government's exhibit list are admissible as business records. Because your client was the COO and President of Theranos, many others are admissible as statements of agents or for non-hearsay purposes. The government anticipates that the vast majority of exhibits offered in the *Balwani* trial will be admissible under multiple hearsay exceptions (or for non-hearsay purposes), limiting any alleged need for further disclosure. We further submit that it serves no purpose to itemize now portions of 302s or grand jury testimony or testimony from prior proceedings to litigate wholesale Rule 801(d)(2)(E) issues; we are pleased to provide you with notice of particular statements within a reasonable time before related witnesses are called.

Nonetheless, in response to your inquiry and in an effort to avoid unnecessary motion practice, the government respectfully provides notice that it may seek to introduce under Rule 801(d)(2)(E) exhibits authored by and statements of [redacted],

[redacted], and/or co-Defendant Elizabeth Holmes, in particular in text messages from co-Defendant Holmes to Defendant Balwani, video or audio recordings of co-Defendant Holmes, other post-investment statements made by co-Defendant Holmes, notes to herself made by co-Defendant Holmes, or emails from other co-conspirators related to the two schemes to defraud. The following is a non-exhaustive list reflected in the following exhibits including but not limited to: Exhibits 1221, 1253, 1348, 1349, 1616, 1647, 1648, 1651, 1652, 1653, 1657, 1718, 1719, 1731, 1739, 1741, 1754, 1953, 2065, 2212, 2274, 2283, 2367, 2368, 2431, 2476, 2580, 2851, 2889, 2949, 3152, 3224, 3278, 3716, 3717, 3727, 4316, 5387, 5470.

We further draw your attention to the following categories of statements the government may seek to introduce under Rule 801(d)(2)(E): (1) statements by co-Defendant Holmes during Surekha Gangakhedkar's exit interview with Ms. Holmes in or around September 2013, (2) statements by co-Defendant to Adam Rosendorff in or around September 2013 relating to the commercial launch and/or in or around the fall of 2014 at the time of his departure, (3) statements by unindicted coconspirators within the Newark laboratory, and (4) statements by Theranos's customer service representatives.

The government expressly reserves the right to identify additional exhibits and statements as pretrial preparation and the trial itself progresses.

Very truly yours,

STEPHANIE M. HINDS
Acting United States Attorney

/s/
ROBERT S. LEACH
JEFF SCHENK
JOHN C. BOSTIC
KELLY I. VOLKAR
Assistant United States Attorneys

EXHIBIT 42

(UNREDACTED EXHIBIT FILED UNDER SEAL)

United States Attorney
Northern District of California

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(510) 637-3680
Fax: (510) 637-3724

June 26, 2020

By Email

Lance Wade, Esq.
Kevin Downey, Esq.
Katie Trefz, Esq.
Amy Saharia, Esq.
Williams & Connolly LLP
725 Twelfth Street, N.W.
Washington, DC 20005

Re: *United States v. Holmes*, CR 18-258 EJD

Dear Counsel:

In compliance with the Court's April 15, 2020 Minute Order, and Criminal Local Rule 16-1(c)(1)-(4), the United States respectfully provides the following supplemental disclosure relating to co-conspirator statements. The government intends to offer under Federal Rule of Evidence 801(d)(2)(E) statements by the individuals listed in Section III of its Bill of Particulars dated March 26, 2020, and Ramesh Balwani and [redacted], which are summarized or reflected verbatim in the government's Exhibit List (served today) and FBI FD-302 reports and memoranda of interview, agent notes, SEC investigative testimony, Grand Jury testimony, and deposition testimony in parallel litigation (*SEC v. Balwani*, *Partner Investments, L.P. v. Theranos, Inc.*, *In re: Arizona Theranos, Inc. Litigation*, and *Colman v. Theranos, Inc.*) produced to date, including, without limitation:

- [redacted]
- Balwani's statement to Tyler Shultz: "Before I get into specifics, let me share with you that had this email come from anyone else in the company, I would have already held them accountable for the arrogant and patronizing tone and reckless comments." PFM-DEPO-00001153.
- Balwani's statement to Erica Cheung "that made it clear to me that sort of the values of the company and my own personal values did not align." PFM-DEPO-00004951.

- Balwani's statement to Cheung: "I am already extremely irritated by unplanned runs of PT samples around Vitamin D and others and how it was handled and communicated when no one from Edison team was included, provide opportunity to prepare, provide feeback before running these samples on serum on Edisons." PFM-DEPO-00004973.

- Balwani's statement to Cheung and others on November 30, 2013 regarding QC Controls for Vitamin D didn't pass: "This is beyond unacceptable performance." PFM-DEPO-00005095.

- Balwani's response with "lip service" to Rosendorff stating upper limits of quantitation were not calculated. US-REPORTS-0007376.

- Balwani's statement that he did not want any qualifying remarks on patient reports. US-REPORTS-0007378.

- Bawlani was hostile other times Rosendorff raised issue. US-REPORTS-0007379.

- Balwani's statement to Sarah Cabayan that she did not have authority to order a sample to be recollected and that only he and Holmes did. US-REPORTS-0000399.

The government further notes that, to date, it has not identified a statement excluded from the hearsay definition only under Federal Rule of Evidence 801(d)(2)(E) and not under other provisions of Rule 801(d), such as Rule 801(d)(2)(B) & (C) (adopted or authorized admissions) and Rule 801(d)(2)(D) (statements by a party's agent or employee). The government reserves the right to argue that the statements identified above are not within the definition of hearsay in

/ /

Rule 801(c) and/or are excluded under other provisions of Rule 801(d). The government further reserves the right to argue that such statements fall within an exception to the hearsay rule in Rule 803.

Very truly yours,

ADAM A. REEVES
Attorney for the United States,
Acting Under Authority Conferred
By 28 U.S.C. § 515

/s/
ROBERT S. LEACH
JEFFREY SCHENK
JOHN C. BOSTIC
VANESSA BAEHR-JONES
Assistant United States Attorneys

EXHIBIT 43

FR T-4
OMB No. 7100-0019
Approval expires March 31, 2011

BOARD OF GOVERNORS OF THE FEDERAL RESERVE SYSTEM

Statement of Purpose for an Extension of Credit by a Creditor (Federal Reserve Form T-4)

Name of Creditor

This report is required by law (15 U.S.C. 78g and 78w; 12 CFR 220).

The Federal Reserve may not conduct or sponsor, and an organization (or a person) is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Public reporting burden for this collection of information is estimated to average 10 minutes per response, including the time to gather and maintain data in the required form and to review instructions and complete the information collection. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Secretary, Board of Governors of the Federal Reserve System, 20th and C Streets, N.W., Washington, DC 20551; and to the Office of Management and Budget, Paperwork Reduction Project (7100-0019), Washington, DC 20503.

Instructions

1. This form must be completed only if the purpose of the credit being extended is *not* to purchase, carry, or trade in securities *and* the credit is in excess of that otherwise permitted under Regulation T. (See § 220.6(e)(2)).

2. Please print or type (if space is inadequate, attach separate sheet).

Part I To be completed by customer(s)

1. What is the amount of the credit being extended? $10,000,000 (USD Ten million only) (USD 10 million only)

2. The borrower acknowledges that no part of this credit will be used to purchase, carry, or trade in securities. The purpose of the credit is described in detail as follows:

Funding for business operations and activities, ramping up operations.

3. Are any of the securities listed in Part II to be delivered, or have any such securities been delivered from a bank, broker, dealer, or other person on a "delivery against payment" basis? ☐ Yes ☑ No

I (We) have read this form and certify that to the best of my (our) knowledge and belief the information given is true, accurate, and complete.

Signed: [signature] 8/13/09
Borrower's signature Date
Elizabeth Holmes
Print or type name

Signed:
Borrower's signature Date
Print or type name

This form should not be signed if blank.

A borrower who falsely certifies the purpose of a credit on this form or otherwise willfully or intentionally evades the provisions of Regulation T will also violate Federal Reserve Regulation X, "Borrowers of Securities Credit."

EXHIBIT 44

Confidential

July 7, 2016

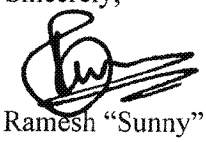
Theranos, Inc.
Attn: Elizabeth Holmes, Chief Executive Officer
1601 Page Mill Rd.
Palo Alto, CA 94304

Ms. Holmes:

My retirement as an officer of the Company, including as President and Chief Operating Officer, was effective May 11, 2016, when the Company issued a press release describing my retirement. Since then, I have remained an employee of the Company and have consulted from time-to-time on various subjects when requested to do so; I have also used the balance of my accrued paid time off. My employment with the Company ended as of today.

As you know, I have not attended a meeting of the Board of Directors since April 12, 2016. Since then, I have not received notice of and have not attended either Board meetings or any meeting of any committee of the Board. My resignation as a director of the Board therefore was effective as of April 13, 2016.

Sincerely,



Ramesh "Sunny" Balwani

Date: July 7, 2016.

cc: Theranos Board of Directors
Mona Ramamurthy